Dispensing of Pharmaceuticals II

Learning Module

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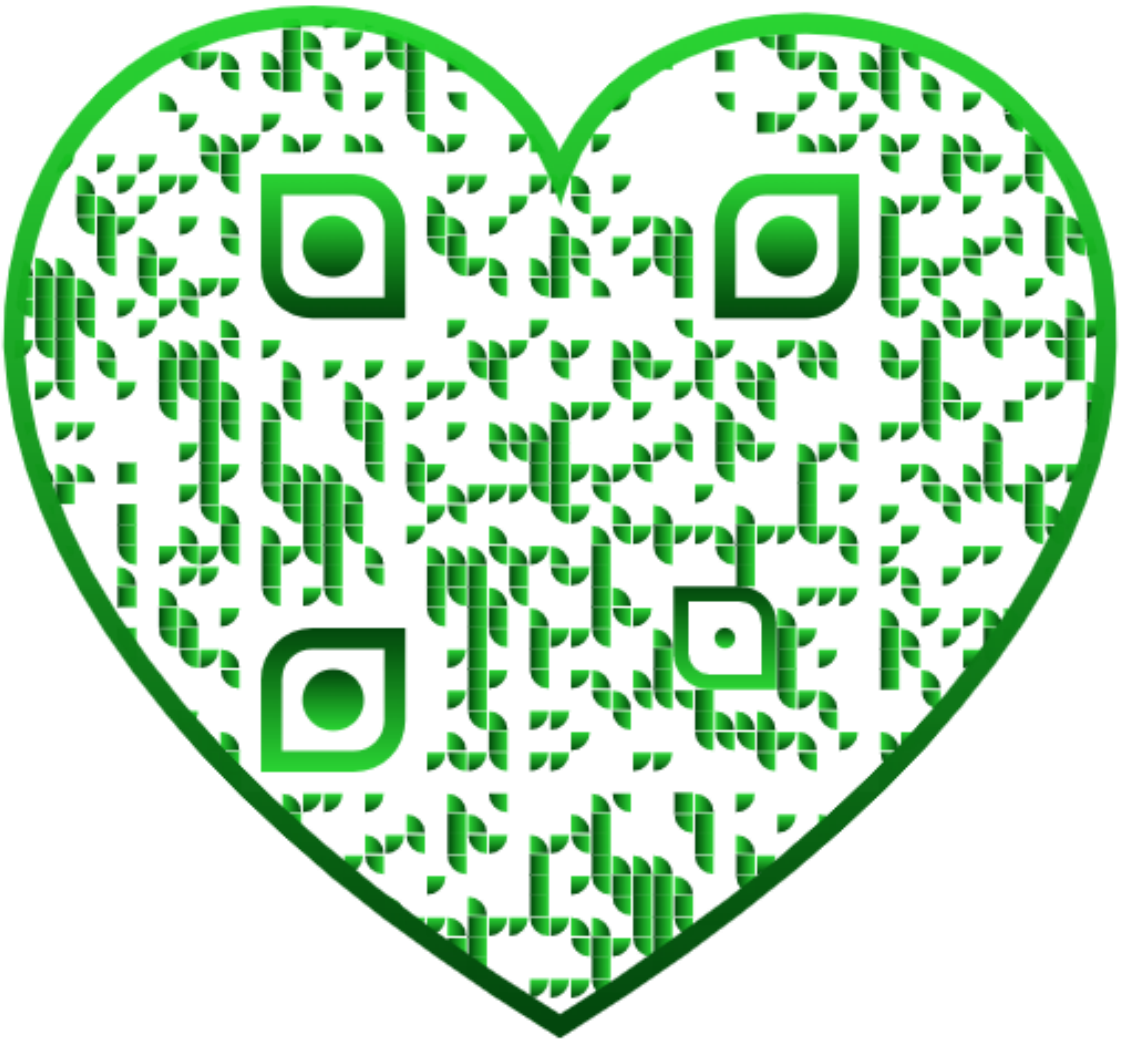

Preface

In response to the critical shortage of Pharmacy professionals in Oromia region, a group of experts from universities and colleges in Oromia region have developed an Outcome based TVET Model curriculum for Pharmacy Level II-IV programs in October, 2017 with the leadership of Oromia Regional Health Bureau.

The outcome based curriculum was developed in reference to the level based 2011 Ethiopian Occupational standard. The guiding principle in the development of the outcome based curriculum was to train Pharmacy professionals in focused, time efficient and outcome based approach, and to fill the existing pharmacy work force shortage in the region with competent professionals.

The key features of the outcome based curriculum include the use of variety of teaching/learning methods, repeated exposure of trainees to skill laboratories, practical attachment/cooperative training and the delivery of the training in standardized learning modules (information sheets) and skill lab manual/checklists (Operation sheets).

This learning module was developed by a diverse group of experts from higher teaching institutions in Oromia region, experts from Oromia Regional health bureau, Oromia TVET, Oromia COC agency and professional associations.

This Dispensing of Pharmaceuticals II learning Module covers one unit of competency in the level III pharmacy program. The learning module covers both theoretical and practical aspects of the competencies.

Dear Trainee, you are expected to read all information presented in the learning module, attempt all the self-check questions and perform skill activities as per the skill lab learning guide/checklist.

Acknowledgments

This Dispensing of Pharmaceuticals II learning module and skill lab manual for **Hospital/Community assisting Pharmacy Level III Program** was developed by experts from Universities and Colleges in Oromia National Regional State.

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1. Hospital and Community pharmacy services

Instructional Objectives

- Define Hospital Pharmacy Services
- Identify responsibilities of hospital staff
- Identify structure and organization of Hospital pharmacy services
- Describe roles and the major functions of DTC
- Define Community Pharmacy
- Outline the setup, duties and responsibilities of community pharmacy
- Identify pharmacy service organization, staffing and workflow

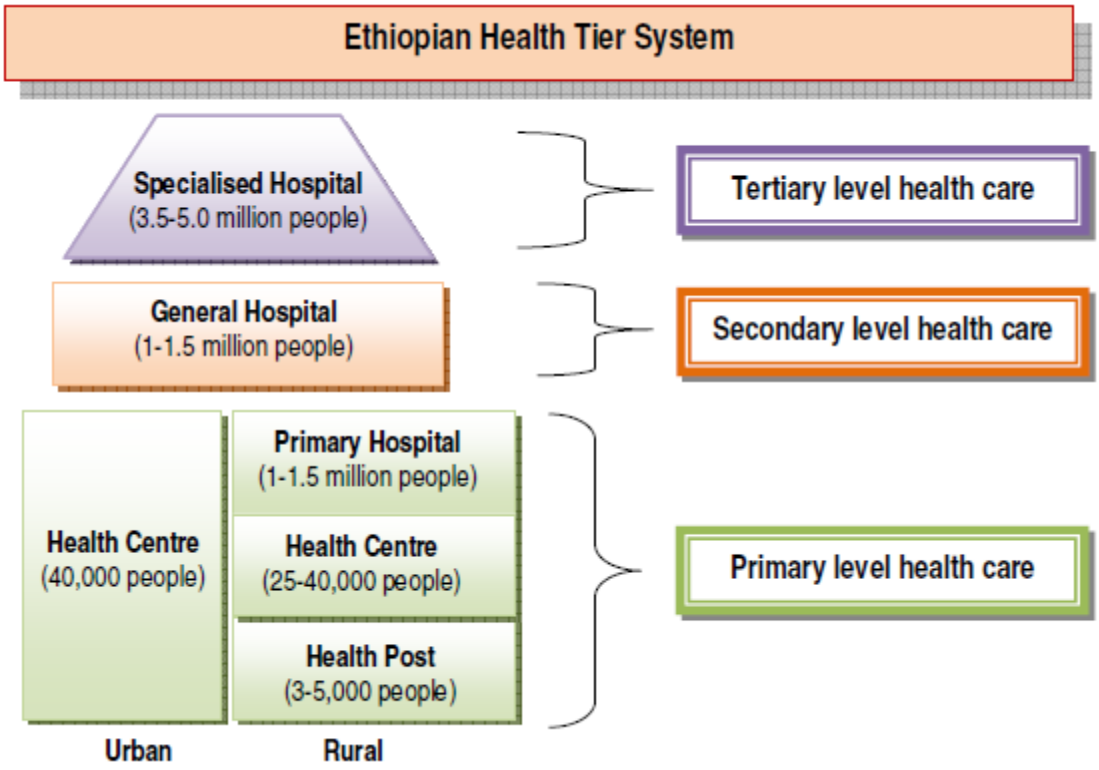
1.1 Introduction to pharmacy

Pharmacy is vital, since it facilitates and enables pharmacy professional to fully exploit their substantial knowledge and expertise in areas such as pharmacology, pharmaceutics, chemistry and therapeutics within a clinical context. The practice of pharmacy aimed at providing and promoting the best use of drugs and other health care services and products, by patients and members of the public. It requires that the welfare of the patient is the pharmacy professional prime concern at all times.

1.2 Health service delivery system in Ethiopia

The Ethiopian health service is structured into a three tier system. These levels are:

a) The primary care level that has three kinds of service points – health posts, health centers and primary hospitals.
b) The secondary care level is comprised of General Hospitals.
c) The tertiary care level is comprised of Specialized Hospitals



Hospitals can be classified in different ways

1. **Based on type of service**
   a) General hospitals
      - Provide general care to patients with any type of illness (medical, surgical, pediatric, psychiatric, and maternity).

   b) Specialized Hospitals
      - Restrict care provided to special conditions (cancer, psychiatric, pediatric, maternity)

   c) General Specialized hospitals
      - provide specialized care to many types of patients

2. **Based on length of stay**
   a) Short-term hospital
      - the average length of stay of the patient is less than 30 days
      - General hospitals are short-term hospitals

   b) long-term hospitals
      - the average length of stay of the patient is 30 days or longer
      - Specialized hospitals are long-term hospitals

3. Based on ownership

a) Government hospitals: Federal, Regional, Zonal, Hospitals or City Hospitals

b) Nongovernmental Hospitals

i) Non-profit: church-related (missionary hospitals)

ii) For profit: individual, Partnership, corporation

4. Based on be capacity/bed numbers

a) Small hospital – less than 100

b) Medium hospital- 100 to 199

c) Big hospital-200 to 500

d) Very big hospital-greater than 500

Functions of Hospitals

Traditionally, the hospital's basic purpose for existence has been the treatment and care of the sick and injured. In conjunction with this basis function, hospitals has been concerned with other functions. The four fundamental functions of hospitals are patient care, teaching/education, research and public health (preventive medicine)

Administration of Hospital

Governing body/Board

- A well-functioning Governing Board that includes representatives from the hospital's community that have impact on the quality and efficiency committed to creating and maintaining a strong bond between the hospital and the community.
- The establishment of a Governing Board builds in autonomy to do what is necessary to provide quality care and accountability to those served for the results of that care.

Officers of the Board

- The Governing Board should appoint three to five Officers, who form the Executive Committee of the Board.
  - ☆ The Chairperson
  - ☆ The Vice-Chairperson
  - ☆ The Secretary of the Governing Board
  - ☆ Additional Officers like immediate past chairperson may be appointed as necessary.

Chief Executive Officer (CEO)/Chief Executive Director (CED)

- A qualified CEO/CED should have a diverse set of leadership, management skills and considerable healthcare/hospital experience as a clinician or management professional.

> ☞ ***Dear trainer read/refer roles and responsibilities of governing board and CEO/CED from Ethiopian Hospital Services Transformation Guidelines, September 2016.***

Hospital Senior Management Team (SMT)

- Responsibilities
  - ☞ Attend ordinary and extra-ordinary meetings, respecting the time;
  - ☞ Accept and implement a decision passed by the majority;
  - ☞ Prepare for each meeting by reading agendas, minutes of the previous meeting and other documents distributed for consideration;
  - ☞ Follow up on any actions agreed by the SMT in a timely manner; and
  - ☞ Maintain confidentiality on all matters discussed by the SMT.

Common Clinical Department/Services of Hospital

The common clinical departments/Services are:

- Emergency Medical Services
- Outpatient Services
- Inpatient Services
- Maternal, Neonatal and Child Health Services
- Pharmacy Services
- Laboratory services
- Radiological and Imaging Service
- Rehabilitative and Palliative Care

Hospital Staff

- Administrative staff/supportive staff: support the medical staff by availing all necessary resources for clinical service.
- Medical staff: responsible for providing all clinical services to patients

Types of medical staff

There are two types of hospital staff:-

a) Open staff hospital: allow external specialists to work

b) Closed staff hospital: all patient care provided only by the attending/active medical staff

Medical staff comprises of:

a) Active medical staff: involved in regular patient care
b) Consulting medical staff :specialists consulted by the active staff on complicated cases
c) Honorary medical staff: physicians who have been active in the hospital but who are retired honor because of outstanding contribution
d) Resident medical staff : provide specific patient care services from which they receive education and experience

Duties and responsibilities of the Medical staff

- Providing professional care to patients
- Maintaining efficiency
- Self-government
- Advising and assisting the CEO and governing board

1.3 Hospital pharmacy services

Hospital pharmacy is the organization or department of the hospital that manage procurement, storage, preservation, packaging, compounding, preparation, dispensing or distribution of medicines in hospital.

1.3.1 Operational standards of Hospital pharmacy services

- The hospital
  - provides quality pharmaceutical products and effective services in its outpatient, inpatient, emergency pharmacy service units and functional compounding service.
  - has a functional Drug and Therapeutics Committee (DTC) that develops and implements interventions promoting the rational and cost-effective use of medicines.
  - has a Medicines Formulary listing of all pharmaceuticals prioritized by VEN that can be used in the facility. The Formulary is utilized and updated annually.
  - ensures execution of good dispensing practices at all dispensing outlets.
  - implements auditable, transparent and accountable pharmaceutical transactions services.
  - provides clinical pharmacy services at inpatient, outpatient and emergency departments.
  - provides drug information services to health care providers, patients and the public.
  - has appropriate paper/computer-based inventory management system.

- has an established system for regular monitoring medication use and safety.
- conducts continuous segregation, documentation & pharmaceutical wastes safe disposal.

1.3.2 Pharmacy service organization and management

Hospital pharmacy services need be effectively managed so as to provide patient-centered services in a manner consistent with standards outlined in this module. To achieve this, the department shall be led by head/ director who are assigned by the hospital management. The department head/director in turn assigns unit coordinators; and team leaders may be formed to execute activities as deemed necessary.

Pharmacy Services Head/Director

The head/director of pharmacy department performs the following activities

- Implements and monitors annual action plans which are approved by the hospital management to fulfill the mission, vision, goals, and scope of hospital services
- Follows developments and trends in health care and hospital pharmacy practice, and communicates to everyone involved in the provision of pharmacy services
- Makes sure national service standards and guidelines pertaining to pharmacy practices are availed and implemented
- Continuously perform workload analysis & alert hospital management for possible action
- Participate in hospital committees and meetings representing the pharmacy department including drug and therapeutics committee (DTC)
- Makes sure that new staffs are properly oriented and supervised.
- Designs and implements professional development programs for all staff as appropriate to enhance their knowledge and skills.
- Regularly evaluates the performance of pharmacy staffs and takes measures accordingly.
- Communicates and collaborates with other departments and services throughout hospital
- Produces and communicates performance reports to the hospital management and relevant government bureaus and agencies

Pharmacy Service Department/units

The pharmacy services of the hospital should be organized as:

- Outpatient pharmacy services unit
- Inpatient pharmacy services unit

- Emergency pharmacy services unit
- Pharmaceutical supply management unit
- Drug information services unit, and
- Compounding pharmacy services units

N.B. Other units shall also be established depending on the hospital complexity and demand. The units should be directed by a registered pharmacist.

1. **Out Patient Pharmacy Services**
   - OPD can be organized in multiple locations (e.g. ART pharmacy, Adult OPD pharmacy, pediatric OPD pharmacy, chronic care pharmacies, MCH pharmacy etc.) depending on the arrangement of the OPD clinics, geographical proximity and complexity of the hospital so as to improve accessibility and convenience to patients.
   - Patient waiting areas at the OPD pharmacy units should be fitted with appropriate seat and should provide enough safety and protection.
2. **Inpatient Pharmacy Services**
   - Depending on patient load, number of beds, and geographical accessibility, there shall be adequate number of dispensaries & specialty pharmacies located near to major wards.
   - These dispensaries should be led by pharmacists (preferably clinical pharmacists).
   - Inpatient pharmacy services should function under the unit dose dispensing and work for 24 hours and 7 days a week.
3. **Emergency pharmacy Services**
   - Emergency pharmacy should be organized near emergency department.
   - The dispensing process should be organized such that pharmaceuticals should reach to the patient as fast as possible.
   - Emergency pharmacy services should function for 24 hours and 7 days a week.
4. **Extemporaneous Compounding Services**
   - The hospital pharmacy should have compounding services with separate premises and equipped with the necessary facilities in fulfillment of relevant regulatory requirements.
5. **Pharmaceutical supply management**
   - To ensure uninterrupted supply of pharmaceuticals, the hospital pharmacy should have pharmaceutical supply management unit.

- The unit has separate pharmaceutical stores for medicines and supplies including consumable medical equipment and lab reagents).
- The overall operation of the unit (selection, quantification, procurement, inventory management, warehousing and distribution) should be coordinated by a dedicated pharmacist and stores should be managed by a separate store managers.

6. **Drug Information Services (DIS)**

- The activities function and projects through which centers achieve their objectives and which constitute their programs of work.
- The hospital pharmacy should have a drug information service unit to effectively provide evidence based and up-to-date drug information for health care providers and patients.

Purpose of Drug Information Services

- To provide comprehensive, objective and evaluated information on drugs with a view to enhancing the rational use of drugs.
- To disseminate technical, scientific and objective information to health care providers.
- To disseminate appropriate drug information to the general public
- To generate, collect, analyze and maintain drug information data
- To design produce and distribute drug information materials
- To give appropriate information on toxicology and poisoning

Establishment

- Drug Information Centers will be established at national level in FMHACA, at regions in Regional Health Bureaus and at Hospitals and Health centers.

Organization

- A National DIS will be organized under the planning and drug information establishment and distribution department of FMHACA.
- Regional FMHACA will be organized under the appropriate pharmacy related department based on structural organization of the RHB. And a health institution DIS will be organized under the pharmacy Department of the Health Institution.

Personnel

At National Level

- Staff members of the planning and drug information establishment and distribution department of FMHACA will run the national FMHACA.

- The staff members shall comprise pharmacists with formal training on clinical use of drugs or clinical based experience and a physician.

At Regional Level

- The regional DIS will be managed by a group/committee, which comprises a pharmacist, physician and IEC officer or a focal person. The pharmacist will be the chairperson of the group/committee.

At Health Institution Level

- The health institution DIS will be coordinated by the pharmacy department.
- The drug information officers (trained physician and pharmacist) will closely work with the Drugs and Therapeutics Committee (DTC) and in consultation with specialists.

Facilities

The Drug information Services:

- Shall have its own office with adequate size and furniture.
- Shall have a direct telephone line and Internet access.
- Shall be equipped with computer, required software and necessary reference materials.

Tasks

The National DIS shall accomplish the following tasks:

- Developing and distribution of Educational and informational materials
- Education and Training
- Conduct Research and/or participate in drug utilization studies
- Supporting and Supervising
- Quality Assurance
- Selection of Drug information and Drug information Source
- Ethical Provision of Drug information Services
- Collaboration with regional, institutional and international centers
- Answering enquires
- Monitoring and evaluation

Tasks of the Regional Drug Information Services

- Developing and distribution of Educational and Informational materials
- Education and Training
- Conduct Research and/or participate in Drug utilization studies

- Selection of Drug information and Drug information Sources
- Quality Assurance
- Ethical Provision of Drug information
- Answering enquires
- Monitoring and evaluation

Tasks of the Health institution Drug Information Services

- Developing and distribution of educational and informational materials
- Education and training
- Conduct research and /or participate in drug utilization studies
- Selection of Drug information and Drug information Source
- Quality Assurance
- Ethical provision of drug information
- Collaboration with national, regional and international centers
- Monitoring and evaluation
- Answering enquiries

Drug Information Services and Clients Category

The drug information request received from clients or drug information provided to audience is categorized as follows: i.e. by drug information clients and/or category of the drug information classification:

Drug Information clients by category

- Health professionals
- Researcher
- Regulatory body
- General public

Drug Information Category

- General product information
- Therapeutic efficacy
- Pharmaceutical Information
- Indication
- Side effects/Adverse effects
- Contraindication

- Drug interaction
- Toxicology
- Drug dosing (both adult, child)
- Special precautions
- Drug use in childhood, pregnancy, lactation, old age, and disease conditions
- Rational drug use
- Drug supply management

7. Clinical pharmacy services

- Clinical pharmacy services are patient-oriented services developed to promote the rational use of medicines, and more specifically, to maximize therapeutic benefits, minimize risk, and reduce cost.
- Clinical pharmacists assume responsibility for managing medication therapy in direct patient care settings (inpatient, outpatient and emergency).
- They assess patients, identify drug therapy needs and problems, propose care plan, recommend choices and hence contribute to therapeutic decisions thereby improving treatment outcomes. The service should be well integrated with all clinical departments.
- Clinical pharmacy services are provided based on pharmaceutical care principles.
- The delivery of pharmaceutical care involves the following logical processes:
    - Assess the patient's medicine therapy needs and identify actual and potential drug therapy problems (DTP)
    - Develop a care plan to resolve and/or prevent the DTPs
    - Implement the care plan
    - Evaluate and review the care plan

1.3.3 Resources needed for pharmacy services

a) Personnel

- Pharmacy services needs both professional and nonprofessional staff that much with the workload of the department.
    - Professional Staff: - Pharmacists, Druggists, Junior Druggists
    - Nonprofessional Staff: - Data/stock card Clerk, Porters, Cleaners, Cashiers, Pharmacy accountant, Messengers

b) Premises, Equipment and Facilities

- The hospital should have sufficient space for the storage, compounding, counseling and dispensing of medicines and for the conduct of related administrative activities.
- The hospital should ensure availability of equipment to deliver proper pharmacy services including: shelves, computers, software, printers, UPS, tablet counters, lockable cabinets, refrigerators, thermometers, dispensing counters, calculators, etc.
- All service areas should be clearly labeled.
- Access should be controlled to ensure that only authorized personnel enter the premises and that only designated personnel have access to keys.
- All pharmacy service units should have a sink with running water and continuous electricity with power backup (connected to hospital generator).
- Appropriately located toilet should be available. Telephones and internet services should also be available within each service area.

c) Dispensary workflow design and Dispensing flow

Dispensary work flow design

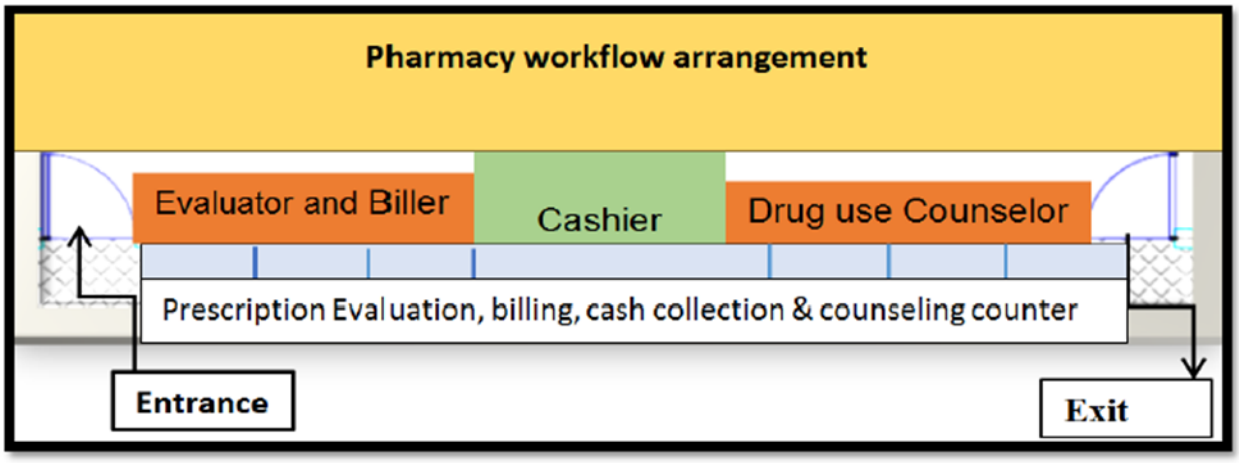


Figure 1.2: Dispensing Workflow design

Dispensing workflow

Once the patient arrives at the dispensing unit with a prescription, he/she passes through the following steps:

1. Receiving, validation, interpretation & checking prescription appropriateness
2. Billing and recording transactions
3. Selection, manipulation or compounding of the medicine

4. Packaging and labeling of the medicine
5. Provision of medicines with counseling
6. Filing the prescription and transaction documents

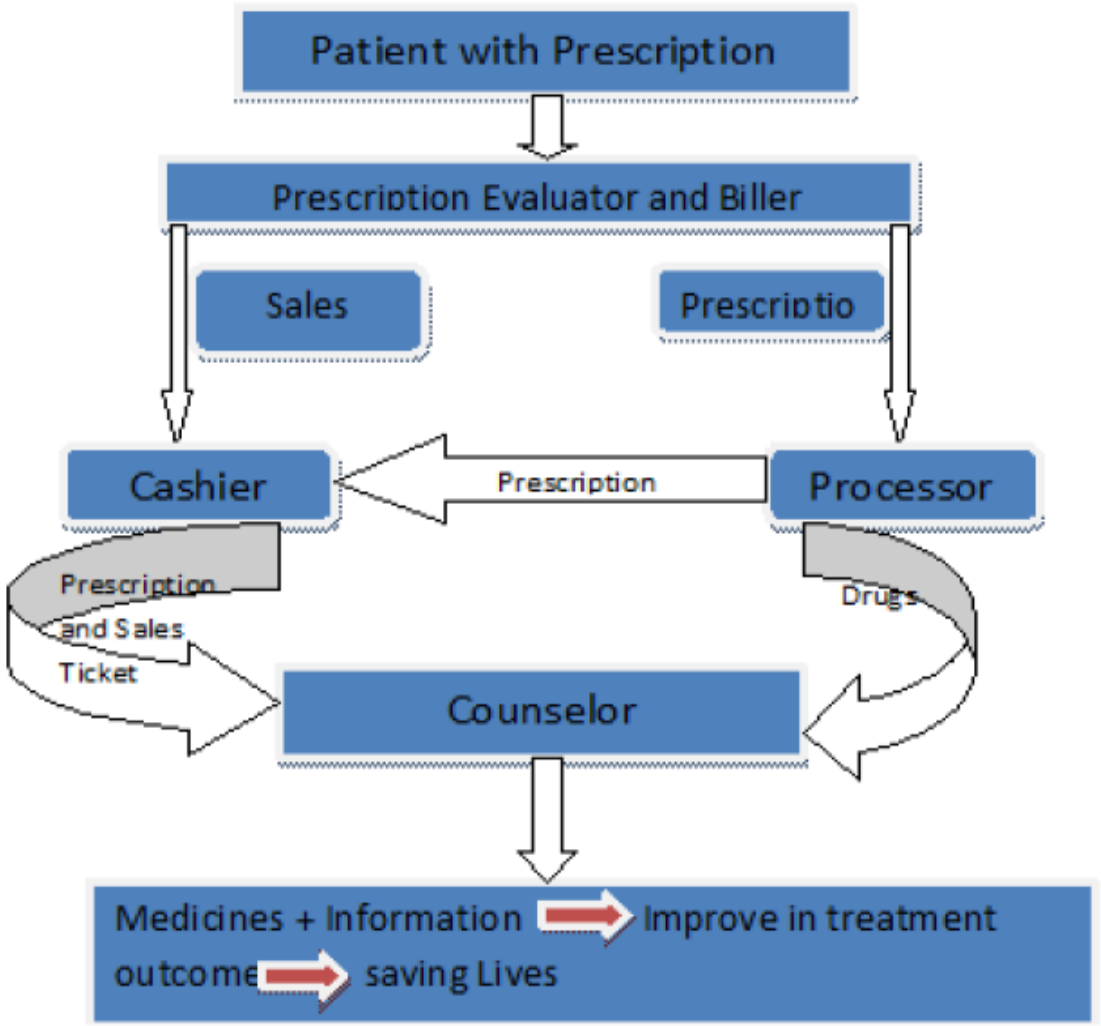


Figure 1.3: Flow of dispensing activities in the dispensary

1.3.4 **Duties and responsibilities of a Hospital pharmacy**

a) Dispensing of Medicine
b) Compounding of Medicine
c) Drug Supplying and Stock management
d) Promoting Rational Drug use
e) Provision of drug information services

1.4 Drug and therapeutics committee (DTC)

Definition: The committee that evaluates the clinical use of medicines, develops policies for managing pharmaceutical use and administration, and manages the formulary system.

Drug and Therapeutics Committee is an essential component of a health facility's effort to improve availability and ensure rational use of medicines. It can provide the leadership and structure to select appropriate medicines for the facility specific medicine list, identify medicine use problems, promote rational use of medicines, and help to reduce pharmaceutical costs.

Drug and Therapeutics Committees has numerous responsibilities that, when performed successfully, will have a positive impact on health care.

Some of the important benefits of a functioning DTC are:-

- Selection of effective, safe, quality & cost-effective medicines for the health facility's medicine list.
- Identification of medicine use problems that can lead to improved medicine use.
- Improved quality of patient care and health outcomes.
- Management of antimicrobial resistance.
- Increase the knowledge of health care providers and patients about rational drug use.
- Manage Adverse Drug Events (ADEs).
- Improve medicine procurement and inventory management.
- Management and control of pharmaceutical expenditures through better management.

1.4.1 Organization of DTC

DTC is usually composed made up of health care professionals from the medical staff (with representatives of the major specialties), pharmacists, nursing personnel, and representatives from administration. Although this mix of personnel would provide the most input from diverse segments of the health care organization, there is no single recommendation that dictates who should be in this committee.

Drug and Therapeutics Committee Members	
At Hospital	**At Health Center**
Chief Clinical Officer	Head of Health center – Chairperson
Head/Director of Pharmacy Services Secretary	Head of Pharmacy Services - Secretary
Relevant person from Pharmacy Departments	Head of Nursing Service – Member
Heads/Representatives of major Clinical Departments – Members	Outpatient Case Team Coordinator – Member
Head of Nursing Service – Member	Head of Laboratory Service – Member
Head of Laboratory Service - Member	Head of finance - Member
Head of Finance Section- Member	

The Members should be appointed by the health facilities management and the committee must maintain a line of authority and support to the management.

For Effective performance, DTC should meet regularly, at least every two months. Two-third of the membership of the committee will constitute a quorum for any meeting. Minutes are prepared for each meeting and distributed to appropriate body, documented well and can be used as an action point for the next meeting.

1.4.2 Functions of DTC

The role of DTC is to ensure availability and rational use of medicines by evaluating the clinical use of medicines, developing the policies for managing medicine use and administration, and developing and managing the medicines list.

The committee has broad responsibilities in determining what medicines will be available, at what cost, how they will be used, and disposed.

The Primary functions of DTC are:-

1. Advising medical, administrative, and pharmacy departments on medicine related issues.
2. Developing policies and procedures to manage medicines.
3. Developing and Maintaining the Health Facility's Medicine List.
4. Identifying and addressing medicine supply and use problems.
5. Managing ADEs (ADRs, Product quality defects and medication errors.)
6. Monitoring and evaluation of medicine use

7. Interventions to promote rational use of medicines
8. Pharmaceutical management issues in the health facility
9. Procurement processes/policy
10. Pharmaceutical promotion (pharmaceutical representatives and promotional literature)

To achieve the above mentioned primary functions of DTC, Chairperson, secretary, members and health facility management will have the following roles and responsibilities.

Some of the Policies and procedures which DTC is expected to develop:

- ✓ New, non-formulary, restricted, investigational medicines

Duties and Responsibilities of the Chairperson

- Ensures that the aims and objectives of the DTC are applied
- Ensures that decisions of the committee are based on scientific evidence, where such evidence is available.
- Establishes good relationship between the committee and health facility management
- Appoints an acting chairperson from the members if he/she is to be absent.
- Presents performance report to health facility management
- Represents the committee in the management meetings and other relevant events
- Calls regular and extraordinary meetings
- Chairs the meetings.
- Communicate relevant decisions and information made by management to DTC

Duties and Responsibilities of the Secretariat

- In consultation with the chairperson, prepares the agenda for meetings and notify to all members of the DTC at least three days before the meeting.
- Collect and circulates all pertinent material for meetings to all members at least three days before the meeting.
- Prepares minutes of meetings & disseminate to all members within 3 days after meeting.
- Follows up the action plans of the committee.
- Ensures that decisions taken by committee are submitted to health facility management.
- Participate in other activities of the committee
- In collaboration with the chair person communicate relevant decisions and information made by management to DTC

Duties and Responsibilities of Members

- Demonstrates professional competence through active participation in the meetings.
- Propose issues that need to be discussed
- Participate in activities of the committee
- Give prior notification if he/she will not be attending the next meeting.
- Communicate decisions of the Committee to the department/case team they represent
- Perform other activities that is assigned for them by the DTC

Duties and Responsibilities of the Health facility

The health facility has also a great deal of responsibility in the establishment and functionality of the DTC. Some of the major responsibilities include:-

- Establish the DTC
- Assign the members by official letter
- Incorporate the activities of the DTC in the annual plan of the health facility
- Allocate the necessary resources for DTC activities
- Provide sufficient time for DTC members to perform their responsibility in the DTC
- Request reports from the DTC regularly and giving timely feedback
- Closely monitor, evaluate and support the DTC etc.

1.4.3 Ethical concerns of the DTC

The committee needs to operate in a manner that ensures transparency and avoids conflicts of interest with manufacturers and distributors of pharmaceuticals and medical supplies. For the committee to maintain objectivity and credibility, a strict ethics policy must be developed and rigorously enforced at all times. The committee should have no relationship with pharmaceutical companies other than a purely professional one that encourages the acquisition of quality medicines and the flow of unbiased information about their products.

Activity: What role do you see for the DTC in improving and maintaining quality in health care system?

1.5 Community pharmacy

Definition: Community or retail pharmacy practice is the practice of providing prescription services to the public. In addition to prescription drugs community pharmacies sell over-the – counter (OTC) medications as well as other health and beauty products. A pharmacy may be owned independently or by a chain. Chains may specialize in pharmacy be part of a broader mass merchandise or food store business.

One of the key characteristics of community pharmacy is close interaction with the patients.

The patient is a customer with alternatives as to where they can bring their business. So good customer service is a requirement, and for this, good interpersonal skills are needed.

Types of Community Pharmacies

1. Pharmacy(run by registered pharmacist)
2. Drug store(by registered druggist)
3. Rural drug vendor(pharmacy technician)

1.5.1 Organization of community pharmacy

A number of space and equipment requirement are dictated by FMHACA.

Storage

- There must be adequate shelving, cabinets, or drawers for storage of medications.
- It is common to see several bays with shelving to hold bottles of medications.
- The medications may be arranged on the shelves pharmacologically according to generic name or they may be arranged according to brand, or trade name.

Scope of community pharmacy

- Processing of prescriptions
- Care of patients or clinical pharmacy services
- Monitoring of drug utilization
- Extemporaneous preparation and small-scale manufacture of medicines
- Traditional and alternative medicines
- Responding to symptoms of minor ailments
- Informing health care professionals and the public
- Health promotion

1.5.2 **Responsibilities of community pharmacy**

- ☆ Dispensing of prescriptions
- ☆ Reviewing the prescriptions
- ☆ Promoting rational drug use
- ☆ Ensuring that prescriptions and medication labels are legal and accurate
- ☆ Advising patients on how and when to take their medicines
- ☆ Advising which medicines to avoid, and possible side-effects of medicines and what to do if they occur
- ☆ Advising patients with OTC medicine they should take to treat a minor ailment
- ☆ Maintain record and registers
- ☆ Prevention and management of drug abuse, misuse and addiction
- ☆ Patient care
- ☆ Nutritional counselling

1.5.3 **Responsibilities of pharmacy assistant**

Assists licensed pharmacist in preparing and dispensing drugs to patients and healthcare providers. Verifies that prescriptions are filled correctly and in a timely manner. Interacts with patients in delivering medications and completing other sales transactions. Receives, records, and stores medications coming into the pharmacy. Maintains stock of prescription medications and informs pharmacist of inventory needs.

Role and responsibilities:

- ❖ Dispenses prescription medication and other medical products to patients under direction of licensed pharmacist
- ❖ Counts pills, labels bottles, prices, and compounds medications to prepare prescriptions for patients as directed
- ❖ Performs administrative duties, including answering phones, receiving and inputting prescription orders, operating cash registers, and restocking inventory
- ❖ Gathers, organizes, and assesses patient information
- ❖ Supplies patients with information and education on their prescriptions
- ❖ Monitors prescription-filling process to ensure compliance with relevant regulations and pharmacy policies

- ❖ Liaises with healthcare providers and patients to obtain correct prescription information
- ❖ Answers patients' questions about their medications under supervision of the pharmacists
- ❖ Takes inventory of drugs on hand and records results
- ❖ Places orders for additional drugs as directed by the pharmacist
- ❖ Maintains electronic patient information
- ❖ Prepares billing information for medications
- ❖ Completes patients' sales transactions for purchase of prescription and over-the-counter medications as well as other pharmaceutical products

Pharmacy Assistant Job Skills:

- ☆ Detail-Oriented
- ☆ Works Well with a Team
- ☆ Strong Customer-Service Skills
- ☆ Excellent Verbal Communication Skills
- ☆ Good Listener
- ☆ Follows Instructions Well
- ☆ Organizational Skills
- ☆ Mathematical Skills
- ☆ Knowledge of Drug Regulations
- ☆ Multi-Tasking Skills
- ☆ Record-Keeping Ability

Self- Check

1. List the function of hospital?
2. Define hospital and Community pharmacy?
3. What is the difference between hospital and community pharmacy?
4. List the different unit/department of pharmacy services?
5. Define drug and therapeutics committee?
6. What is the role of DTC in primary health care?
7. Mention the primary function of DTC?
8. Describe the duties and responsibilities of different members of DTC?
9. Differentiate the role and responsibilities of pharmacy assistant?

Summary

- ☞ Hospital pharmacy services need be effectively managed so as to provide patient-centered services in a manner consistent with standards.
- ☞ The head/director of pharmacy department performs the following activities (in collaboration with other colleagues)develops implements and monitors annual action plans which are approved by the hospital management to fulfill the mission, vision, goals, and scope of services of the hospital.
- ☞ Drug and Therapeutics Committee is an essential component of a health facility's effort to improve availability and ensure rational use of medicines. It can provide the leadership and structure to select appropriate medicines for the facility specific medicine list, identify medicine use problems, promote rational use of medicines, and help to reduce pharmaceutical costs.
- ☞ key characteristics of community pharmacy is close interaction with the patients.

Learning activity Performance test

Critical aspects of the competencies

- ☞ Observation of workplace performance is essential for assessment of this unit
- ☞ Consistency of performance should be demonstrated over the required range of situations relevant to the workplace
- ☞ Where, for reasons of safety, space, or access to equipment and resources, assessment takes place away from the workplace, the assessment environment should represent workplace conditions as closely as possible

a) Knowledge

- ✓ Hospital pharmacy contribution to a health care team.
- ✓ Organization values and philosophy and how they apply to the work of a pharmacy assistant/technician.

b) Skill

- ✓ Use literacy, numeracy and oral communication skills required to fulfill the position in a safe manner as specified by the health care facility
- ✓ Use problem solving skills
- ✓ Use available resources and prioritize workload

2 Pharmaceutical quality assurance

At the end of this chapter you will be able to:

- Define Pharmaceutical quality assurance
- Describe how medicines quality are assessed and ensured
- Describe the role of DTC in pharmaceutical quality assurance
- Apply Quality Medicines Dispensing techniques

2.1 Introduction to pharmaceutical quality assurance

The assessment and assurance of the quality of medicines is an integral part of national medicine control system, without which, any health service is evidently compromised. Medicine control Authority of each country has the responsibility for the development of guidelines, norms and administrative regulations for quality surveillance.

In general, the manufacturers and the distributors (including importers, wholesalers and medicine retail outlets) are responsible for the quality of medicines they manufacture or distribute. The desired quality of medicines can be achieved by strict adherence to specifications recommended by medicine control authority. It is evident that the quality of dispensed medicines can be determined by the quality of dispensing process.

Dispensing practice should mean more than simple issuance of the prescribed or requested items in order to achieve the desired therapeutic goal. The quality and quantity of the dispensed items as well as appropriate medicine information mainly determine the success of medicine therapy.

Key definition:

- **Pharmaceutical quality assurance:** is the sum of all activities and responsibilities required to ensure that the medicine that reaches the patient is safe, effective, and acceptable to the patient.
- **Visual inspection:** is the process of examining products and their packaging to look for problems and product quality.

Goal of Pharmaceutical Quality Assurance

- Ascertain medicine reaching patient is safe, effective & of appropriate (standard) quality.
    - Obtaining quality products that are safe and effective through structured selection and procurement methods

- Maintaining quality products through the appropriate storage, distribution, monitoring, and use by prescribers, dispensers, and consumers

2.2 Comprehensive quality assurance program

- Medicines are selected on the basis of safety and efficacy, in an appropriate dosage form with the longest shelf life
- Suppliers with acceptable quality standards are selected
- Medicines received from suppliers and donors are monitored to meet quality standards
- Medicine packaging meets contract specifications
- Obtaining quality products that are safe and effective through structured selection and procurement methods
- Maintaining quality products through the appropriate storage, distribution, monitoring, and use by prescribers, dispensers, and consumers

2.3 Impacts of low quality medicines

Poor-quality medicines may cause a number of serious problems including:-

- Lack of therapeutic effect that may lead to prolonged illness or death
- Toxic or adverse reactions
- Waste of limited financial resources
- Diminished program credibility, making healthcare system less effective & desirable.

2.4 Pharmaceutical quality assurance framework

The following five elements are critical to achieving the expected treatment outcome. Using a pharmaceutical product to treat a patient presumes that the:-

1. Active pharmaceutical ingredient(API) shown to be safe & effective for treatment
2. Product is of suitable quality to provide an effective outcome
3. Prescriber has accurately identified the need for the treatment
4. Prescriber or dispenser has properly instructed the patient on how to use the product
5. Patient complies with the prescribed regimen correctly

2.5 Determinants of medicine quality

- **Identity**: the identity test should confirm the existence of the active ingredient(s) indicated on the label. This characteristic is generally the easiest to check.
- **Purity**: in addition to API, pharmaceuticals are made with ingredients added for bulk, consistency, or color that should not contain potentially harmful contaminants. The product should not have significant quantities of other products from cross-contamination.

Strength or potency:

- The medicine should contain the declared amount of API.
- Harmful by-products of degradation must be absent or should be below defined limits.
- Most pharmacopoeias specify an average content range, such as 90 to 110 percent of the amount written on the label, rather than an exact amount.
- To ensure a long shelf life, manufacturers often produce pharmaceuticals with the maximum allowable amount (for example, 110 mg rather than 95 mg), which provides a margin of safety for slight losses in strength or potency over time.

Uniformity of dosage form:

- The consistency, color, shape, and size of tablets, capsules, creams, and liquids should not vary from one dose to the next.
- Any lack of uniformity may suggest problems with other quality parameters such as identity, purity, or strength or potency.
- Lack of dosage uniformity may not influence the safety or effectiveness of a medicine, but it does reflect a lack of good manufacturing practices, which could influence the acceptability of a product to pharmacists, medical practitioners, and patients.

Bioavailability

- Bioavailability refers to the speed and completeness with which a pharmaceutical administered in a specific form (tablet, capsule, intramuscular injection, subcutaneous injection) enters the bloodstream.
- The bioavailability of a product may depend on the other ingredients used in the formulation, such as solvents, binders, coloring agents, and coatings, or how ingredients are combined.

Stability: to be useful, a pharmaceutical must retain its properties within specified limits, such as particular storage conditions.

Quality of medicine is assessed by:

a) Inspection of products on arrival
   - visual inspection
   - product specification review (including expiration dates)

b) Laboratory testing for compliance with pharmacopoeia standards

c) Bioavailability data

Procedures to establish comprehensive quality assurance program is classified into 3 categories.

1. Procedures to ensure only products that meet current standards for quality are bought.
   - Careful product and supplier selection
   - Certificate of analysis for each batch of product
   - Certification of good manufacturing practices
   - Batch certification (WHO-type certificate of a pharmaceutical product)
   - Inclusion of detailed product-quality specifications in the contract
2. Procedures to verify that shipped goods meet the specifications.
   - Pre- and post-shipment inspection
   - Analytical pharmaceutical testing
3. Procedures to monitor and maintain the quality of pharmaceuticals from the moment they are received until the medicine is finally consumed by the patient.
   - Proper storage and distribution procedures
   - Appropriate dispensing
   - Instructions to the patient on proper use of medications
   - Product defect and pharmacovigilance reporting programs

The national procurement agency would have a responsibility of monitoring the quality of products. The DTC should ensure that it maintains effective communication with the:

- Drug Regulatory Authority (FMHACA) and its branches
- Pharmaceutical fund and supply agency (PFSA) and its branches
- Regional medicine regulatory body
- Regional/zonal Health office
- Pharmacy unit of the health facility

Responsibilities of different actors in ensuring quality of Medicines

a) Drug and Therapeutics Committee (DTC)

- ☞ Selecting medicines for the medicines list and procurement
- ☞ Advising on appropriate storage and transportation of medicines
- ☞ Coordinating medicine quality monitoring
- ☞ Ensuring quality defect report communicated to appropriate body

The DTC should work closely with the departments of the respective health institution, including pharmacy, nursing, medical, and supply management staff, to ensure that pharmaceutical quality assurance procedures are practiced throughout the system. All health care personnel should be enlisted and encouraged to participate in a comprehensive QA program to ensure that medicines are procured, stored, administered, dispensed, and used correctly.

The DTC should work with regulatory agencies, the procurement department, suppliers, pharmacies, physicians, and patients to analyze, evaluate, and take action on quality complaints of products. This function of the DTC is vital to ensure that medicines of good quality are available. Complaints about quality should be analyzed and recommendations developed to deal with quality defects.

b) Health facilities Pharmacy units are responsible for

- ☞ Inspecting products
- ☞ Reporting, and taking action on quality defects
- ☞ Ensuring appropriate storage in the warehouse, pharmacy, and departments.
- ☞ Using appropriate containers for dispensing
- ☞ Instructing patients on appropriate use of medicines

c) Health care providers

- ☞ Monitoring and promoting quality assurance in their facilities
- ☞ Reporting quality defects

d) Patients

- ☞ Storing medicines correctly
- ☞ Taking medicines correctly
- ☞ Reporting quality defects to health facility/ health care provider

e) Health facility management

- ☞ Monitor and ensure that systems for medicines quality assurance are in place.

2.6 Techniques for quality medicines dispensing

The main aim of quality dispensing is to maintain the quality of the dispensed medicines for their specified shelf-life and ensure appropriate use of the medicine by the patients. An important aspect of quality dispensing concerns the packaging and storage of medicines. The techniques that lead to quality dispensing may be accumulated through training and/or experience.

The most useful techniques to ensure quality in dispensing include:

- Maintenance of records on what medicines and products have been issued.
- Maintenance by pharmacy department of a daily list of medicines in stock to inform prescriber which medicines available thereby ensuring only these medicines prescribed.
- A two prescription system whereby two separate prescriptions are written one for medicines available in the pharmacy and one for those that are not but can be ordered which helps to avoid rewriting of prescriptions.
- Adherence to specifications for storage conditions.
- Adherence to specifications for containers for repackaging
- Keep written procedures for compounding
- Dispensing only one prescription at a time
- Avoid dispensing when dizzy, in stress, etc.
- Double checking of the name, dosage form, strength amount to be dispensed as well as the information on the label
- Organize Medicine and Therapeutic Committee at health institution level and participate.

Self-Check

1. Define drug quality assurance.
2. List characteristics of comprehensive quality assurance program.
3. Describe the impacts of poor quality medicines.
4. How is the quality of medicine assessed?
5. How is the quality of medicine assured?
6. What is the role of DTC in improving and maintaining quality in health care system?

Summary

- ☆ The purpose of quality assurance in pharmaceutical supply systems is to help ensure that each medicine reaching a patient is safe, effective, and of acceptable quality. A

comprehensive quality assurance program includes both technical and managerial activities, spanning entire supply process from pharmaceutical selection to patient use.

☆ Established quality standards are published periodically in pharmacopoeias and in some government publications.

☆ For the purposes of primary health care, the most important characteristics of a pharmaceutical product are identity, purity, strength, potency, uniformity of dosage form, bioavailability, and stability.

☆ Pharmaceutical quality is affected by starting materials, manufacturing process, packaging, transportation and storage conditions, and other factors; these influences may be cumulative.

☆ If a pharmaceutical does not meet established quality standards, passes its expiration date, or has been degraded by storage conditions, the possible consequences are:-

- Lack of therapeutic effect, leading to prolonged illness or death
- Toxic and adverse reactions
- Waste of limited financial resources
- Loss of credibility of the health care delivery system

☆ A comprehensive quality assurance program must ensure the following:-

- Pharmaceuticals selected have been shown to be safe and efficacious for their intended use, are presented in an appropriate dosage form, and have the longest possible shelf life.
- Suppliers with acceptable quality standards are selected.
- Pharmaceuticals received from commercial suppliers and donors meet specified quality standards at the time of delivery.
- Packaging meets contract and usage requirements.
- Repackaging activities and dispensing practices maintain quality.
- Storage and transportation conditions do not compromise product quality.
- Product quality concerns reported by prescribers, dispensers, and consumers are properly cataloged and addressed.
- Product recall procedures are implemented to remove defective products.

☆ A quality assurance program should include training and supervision of staff members at all levels of the supply process and a suitable information system. Often, public officials

must balance the costs of establishing and maintaining quality assurance systems against the benefits of having safe and effective medicines.

☆ Medicine safety and quality issues are critical to a health care system. The DTC is in a position to have a significant impact on preventing and managing these problems. The DTC should monitor, support and follow the reporting of ADEs to the responsible body.

Learning activity Performance test

Critical aspects of the competencies

i. Knowledge
   - ✓ Principles and practices of pharmaceutical quality assurance
   - ✓ Medical/pharmaceutical terminology appropriate to hospital pharmacy work

ii. Skill
   - ✓ Take into account opportunities to address waste minimization, environmental responsibility and sustainable practice issues
   - ✓ Apply pharmacy policies, procedures, standards and guidelines

3. Pharmacy law and ethics

At the end of this chapter you are able to

- Define Terminologies
- Describe the pharmaceutical Law
- Identify the structure, organization, duties and responsibilities of FMHACA
- Describe the Pharmaceutical Code of Ethics
- Define and describe law governing pharmacy practice
- Review the Current Pharmaceutical Laws and Regulations in Ethiopia

4.1 Historical perspective of Pharmacy profession

The practice of pharmacy parallels the history of civilization. Man's desire to protect himself against pain, disease and injury gave rise to the art of selecting, extracting, compounding and preparing medicines from plant, animal and mineral sources which are found in nature in the environment around him. Prior to the industrial production of pharmaceuticals, extemporaneous compounding tailored to individual patient's needs was the main source of drug supply.

There were also other significant progresses made in the different areas of pharmacy practice, including hospital pharmacy, community pharmacy, pharmaceutical industry, regulatory authority, drug research, pharmacy training program and other health care promotion services. Moreover, pharmacy professional currently practicing in the health care systems, especially in the developed world, have extended their activities from focusing on the supply of medicines to assuming an increasingly clinical and advisory role, thus taking effectively to patient care decisions within the multidisciplinary healthcare teams.

As pharmacy profession plays such a crucial role in healthcare system of nation, and no doubt, there are bound to be numerous ethical issues that would arise during the professional practices.

Definition of some Terms

Profession

It is employment, not mechanical and requiring some degree of learning. It is an occupation requiring knowledge of some department of learning or science and special training. e.g. law, architecture, medicine, accounting.

Professional: Professional is a person doing or practicing a profession.

Professionalism:-a professional character, spirit or methods.

Pharmacy: is a profession concerned with the art and science of preparing materials from natural and synthetic sources for use in the diagnosis, treatment and preventions of diseases.

Pharmacy professional meet the basic characteristics of a professional which include:

- ☆ Specialized body of knowledge necessary to practice pharmacy.
- ☆ Provision of essential services within the society in their field of specialization.
- ☆ Mutual trust between the pharmacist and his/her patron because the receiver of these services, in most cases, does not have capacity to assess the quality of services rendered.
- ☆ Exclusive right to practice the profession ethically after receiving the license from the appropriate regulatory authority.

Ethics

The term ***Ethics*** is derived from ***Ethos*** (Greek), and ***Morality*** from *Mores* (Latin).

Ethics is the science of moral value.

Morality is *a system of rules for guiding human conduct & principles for evaluating those rules*.

The basic foundation of ethical behavior is the basic concept: "Do Good and Avoid Evil". Ethics and law are related to each other in that both share the social purpose of encouraging the right conduct. Whereas law attempts to achieve its purpose through the sovereign power of the government, ethics, especially professional ethics, attempts to achieve it without the intervention of the government. Therefore, law is enforced by the government, while ethics is a principle achieved by the voluntary self-discipline of professionals.

Professional Ethics

- Professional ethics is the moral principle, which should guide members of the profession in their dealings with each other & with their patients, the patrons, the state etc. One characteristic of members of a profession is a collective & disciplined concern of group.
- The attitude of the professional should be altruistic and unselfish concern for the welfare of others. Ethics is therefore, an inherent characteristic of professional behavior.

Adherence to professional Ethical standards is expressed through:-

- ➢ Taking a professional Oath
- ➢ Accepting professional Code of Ethics.

Code of Ethics

- The rules of conduct based on moral values, which are stated by a recognized association are identified as Code of Ethics.

Moral Versus Ethics in Work place

- ☞ The pharmacy technician has a clear responsibility to the patient on many levels
- ☞ Ethics are morals in the workplace and in the public domain
- ☞ Work ethics will guide your behavior
- ☞ Working within pharmacy guidelines will ensure that patients are getting the best service possible.

4.2 Pharmaceutical law

- The science or philosophy of law governing the pharmaceutical sector.
- Deals with the aspect of law and legal concepts in relation with the practice of pharmacy.
- It is also restrictive like other laws.

"In order to appreciate Law try to imagine what will happen if there is no law."

Pharmaceutical law is needed for the following major reason:-

- ➢ To ensure proper implementation of pharmaceutical policy.
- ➢ To determine role of pharmacy law executive agency, medical practitioners, pharmacy personnel, manufacturers, whole sellers, retail outlets, health institution, and consumers in ensuring a availability, quality assurance, proper storage, distribution & use.
- ➢ To ensure final consumers receive pharmaceuticals of proven quality, safety and efficacy.
- ➢ To ensure the implementation of the pharmaceutical sector as to the required standard.
- ➢ To ensure fair trade in pharmaceutical sector.

Scope of Pharmaceutical Law

- ➢ Substances and items other than drugs that may be covered in the law include: food, cosmetics, poisons, medical supplies, medical device, chemical and reagents, pesticides, insecticides, toilet articles and detergents.

4.3 Laws that regulates Pharmaceutical services in Ethiopia

- The pharmaceutical sector had been regulated by Pharmacy regulation No. 288/64 of 1964. This regulation has been replaced by the Drug Administration and Control Proclamation No. 176/99 of June 1999 which is comprehensive enough to regulate the entire life cycle of pharmaceuticals. This proclamation is currently replaced by Food, Medicine And Healthcare Administration And Control Proclamation No. 661/2009

Organization of the Authority (FMHACA)

The Authority shall have:

1. Board
2. General Manger and Deputy General Manager
3. Directorate

- Regulatory standard setting and information delivery Directorate
- Product registration and licensing Directorate
- Product quality Assessment Directorate
- Health institution and professional registration and licensing Directorate
- Inspection and surveillance Directorate
- Medico-legal service Directorate
- Plan and project coordination Directorate

Major Duties and Responsibilities

- Sets standards of quality, safety and efficacy of drugs and ensure their observance.
- Sets standards of competence and issues, controls, renews, revokes, suspends certificate of competence of drug establishments.
- Evaluates and issues, renews, revokes and suspends drug registration certificate
- Undertake inspection of pharmaceutical premises, establishments & port of entry & exit.
- Prepares categories and revises national list of drugs.
- Formulates police, and prepares draft legislation.
- Control quality of raw and packing materials used for the production of drugs and finished products.
- Prepares standards of quality, safety and efficacy of traditional drugs
- Serves as drug information resource center and controls advertisement and promotion.
- Control production, import, export, distribution and use of Narcotic drugs and Psychotropic substances.
- Conduct and coordinate post marketing drug quality surveillance.
- Issues license for conducting clinical trials, monitors and evaluates the process and authorizes the use of results.
- Creates favorable conditions for the promotion and expansion of drug trade

Scope of Control

Products Regulated by FMHACA:

- Human Medicines
- Radio-pharmaceuticals
- Traditional medicines
- Complementary and alternative medicines
- Medical supplies and instruments
- Food including Food supplement and infant formula
- Sanitary items
- Cosmetics
- Raw and packaging materials

Institutions Regulated by FMHACA:

- Manufacturers
- Importers and wholesalers
- Exporters
- Drug quality control Labs
- Scientific offices
- Specialized Hospitals
- Specialty Centers

Laws governing Pharmaceutical practice in Ethiopia

- Food, Medicine And Healthcare Administration And Control Proclamation No. 661/2009
- Ethiopian Food, Medicine And Healthcare Administration And Control Authority Proclamation No. 661/2009
- Ethiopian Food, Medicine And Healthcare Administration And Control Authority Regulation No. 189/2010
- Food Medicine And Healthcare Administration And Control Councils Of Ministers Regulation No 299/2013
- WHO Framework Convention On Tobacco Control Ratification Proclamation No. 822/2014

4.4 Pharmaceutical code of ethics

Pharmacists are health professionals who assist individuals in making the best use of medications Code of Ethics is intended to state the principles that form the fundamental basis of roles & responsibilities of pharmacists. These principles, based on moral obligations & virtues, are established to guide pharmacists in relationships with patients, health professionals, and society.

4.4.1 Ethical principles and obligations of Pharmacy professional

Pharmacy Professional in Relation to his/her Patients

1. Respect the covenantal relationship between the patient and pharmacy professional with due respect to the autonomy and dignity of each patient in order to promote the good of every patient in a caring, compassionate and confidential manner.
2. Be morally obliged in response to the gift of trust received from the society and, be responsible to help individuals draw optimum benefit from their medications. He/she should also be committed to their welfare as well as to win and maintain their trust.
3. Not show partiality between his patrons. Therefore, he/she should not discriminate between patients by nationality, creed, color, sex, religion, social status, political stand.
4. Not abuse his/her relationship with the patient for personal gain.
5. Dedicate to protect the dignity of the patient and in doing so, he/she should respect the patient's right not to take a drug unless the disease condition requires otherwise by law.

Pharmacy professional in Relation to the Public

The pharmacy professional should:

1. At all times, act in a manner which promotes and safeguards the interest of the public; justifies public trust in that professional knowledge, ability and judgment and, enhances the respect for and reputation of the profession.
2. Offer services in premises which reflect the professional character of pharmacy.
3. In the best interest of the public, provide information about available professional services and be responsible also for providing appropriate public health education on pharmaceutical services
4. Be accountable for any damage that may be inflicted on patron as a result of negligence and/or non-conformity to professional duties and/or breach of professional conduct

5. Be accountable for any damages that may be inflicted upon the patron as a result of obstruction to perform professional obligations by a non-pharmacist owner or employer. This is applicable only if the pharmacist did not report interference with his professional responsibilities immediately to the Drug Regulatory Authority for legal action.

Pharmacy professional in Relation to Fellow Professionals

1. The pharmacy professional should extend all support, respect and cooperation to fellow members of his/her profession whenever they seek scientific and technical information.
2. The pharmacy professional shall have the responsibility to expose any act of misconduct or malpractice committed by a fellow professional to keep up the honor and respect for the profession and to fully cooperate in enforcing the law.

Pharmacy professional in Relation to Other Health Professionals

The pharmacy professional should:

1. Respect the skills and competence of other health care providers and endeavor to develop a team work spirit among them to optimize the health outcomes of patients & public.
2. Endeavor to foster and maintain the role of the pharmacist as an active member of the health care team with expertise in drug related health outcomes.
3. Not recommends a particular medical practitioner to the patient. This, however, does not mean that pharmacist should not advise a patient on basis of nature of his/her complaints.
4. Endeavor to maintain the confidence and trust placed in other health professionals by patients and must refrain from making public comments that could negatively affect their professional reputation or harm the relationship they have with patients.
5. Expose any acts of malpractice committed by other health professionals through the appropriate channel.
6. Not enter into any secret arrangement or negotiations with any health professional by way of giving any offer, commission, etc in return to his/her favor of patronage by recommending his/her establishment.
7. Not be an accomplice to any act of malpractice with other health professionals.
8. Strives to promote health, expand health services and develop teamwork spirit with other health professionals.

Pharmacy professional as an Active Professional Member

1. The pharmacy professional shall actively seek to update his/her knowledge and skills of pharmacy to ensure a high standard of professional competence and must keep abreast with latest advances in his/her area of practice.
2. The pharmacy professional shall strive to join and participate in activities of professional associations and scientific societies with the objectives of promoting the profession.

Pharmacy professional as a Member of the Community

The pharmacy professional should:

1. Keep his/her honor and demonstrate a high standard of personal integrity in the community where he/she lives and shall show concern for social justice and promote the same in the community.
2. Be enlightened & conversant with laws in the country & should be a law-abiding citizen.
3. Participate in social development activities in his/her community
4. Uphold accepted standard of behavior in the community and must refrain from any conduct that might impair the public's confidence in the profession.

4.4.2 Ethical principles and standards in Pharmacy practices

1. Dispensing of Medications in Pharmacy
2. Compounding and Manufacturing of Pharmaceuticals
3. Pharmaceutical Supply Management and Rational Drug Use
4. Handling of Narcotic, Psychotropic and Other Dangerous Drugs
5. Quality Assurance of Pharmaceuticals
6. Promotion and Advertisement of Pharmaceuticals
7. Disposal of Unfit for Use Products
8. Pharmaceutical Regulatory Services
9. Drug Research and Development
10. Pharmacy Education
11. Pharmaceutical Care Practice

4.4.3 Ethical principles and obligations on special ethical issues

1. **The Right to Confidentiality**
   - In the health care arena, individuals typically surrender some measure of privacy to professionals, yet feel that they ought to retain some control over information transferred to health care professionals such as pharmacists.
   - With regard to pharmacy professionals, such records, include but not limited to, prescriptions, patient profiles and reports, which contain information that identifies an individual receiving pharmacy services.
   - Pharmacy professional, as trusted personnel, have an ethical obligation to protect the patient's right of confidentiality.
   - It should be understood, however, that the right to confidentiality cannot be absolute.
2. **Euthanasia and Abortion**
   - Euthanasia and abortion are medical interventions, which do not directly involve the pharmacy professional in the practices. But as a custodian of drugs and medical supplies, the pharmacy professional may be called upon to supply products intended for the above medical interventions.

4.5 Drug registration and control

1. ***Registration***
   - No drug, whether produced locally or imported, shall be put into use unless it is duly registered by the Authority.
   - The registration shall be effected in accordance with the regulations to be issued for the implementation of this Proclamation.
2. ***Certificate of Registration***
   - A registration certificate which remains valid for five (5) years shall be granted for a drug registered pursuant to Article 16 of this Proclamation.
   - The certificate shall show whether the drug is a prescription-drug or non-prescription drug; and also the level of the health institution or drug retail outlet where it shall be available.

3. **Standard of Quality**
    - The Authority shall assure the quality of drugs as per its own pharmacopoeia or the pharmacopoeia of other countries which are recognized by it.
    - No drug, raw material or packaging material which fails to comply with its quality specifications shall be put into use.
4. **Post Marketing surveillance**
    - The Authority shall carry out post marketing surveillance in order to ensure the safety, efficacy and quality of drugs that are put into use.
    - The Authority shall have the power to ban the use, or to revoke the registration, of a drug that was put into use when, later on, it is proved to be ineffective or its risk outweighs its benefit.

4.6 Dissemination of information and advertisement

- No person shall disseminate any drug related information that is meant for professionals and the public unless after their usefulness and correctness is verified and approved by the Authority.
- No person shall cause advertisement concerning drug whether in writing or in any way which is not in compliance with law of trade advertisement, or the directives issued by the Authority, or which is misleading to the public as to their value or effect.

4.7 Packaging materials and label

- No drug shall be put on the market or distributed by any means unless it is duly packed or labeled as provided in the regulations and directives issued to enforce this Proclamation.
- Any drug manufacturer, importer, wholesaler, retailer or health institution shall ensure that all drugs, which he offers for use, are duly packed and labeled.

4.8 Narcotic and Psychotropic substances

Prescriptions

- Only a medical practitioner who is registered and have a special license shall prescribe narcotic drugs.
- Psychotropic substances shall be prescribed by a licensed and registered practitioner.
- No practitioner shall prescribe narcotic drugs and psychotropic substances for himself.

- Narcotic & psychotropic substances shall be prescribed on a special prescription paper
- Management and standard that any prescription for narcotic or psychotropic substances shall fulfill would be set forth in regulation to be issued pursuant to this Proclamation.

Storage

- Narcotic drugs and psychotropic substances and invoices, registers, and prescriptions shall be stored in a lockable metal cupboard or in a special room the key of which shall at all times remain in the hands of the authorized professional.

Disposal

- Any person shall keep damaged, expired, or seized narcotic drugs or psychotropic substances in a separate place and shall dispose them in accordance with the directive to be issued by the Authority pursuant to this Proclamation.

Recording and Reporting

- Any person who is licensed pursuant to this proclamation shall keep records and send reports about narcotic drugs or psychotropic substances in accordance with a directive that shall be issued by the Authority.

4.9 Poisons and radiopharmaceuticals

Poisons

- The Authority, based on international standards, prepare a list of poisons & communicate to all concerned bodies, issue a detailed directive on storage, sale & disposal.
- No person shall manufacture, import and distribute poisons unless he first have obtained a special permit from the Authority.
- Any person, who manufactures, imports or distributes poisons, shall keep detailed records of such poisons in accordance with the directives they may be issued by the Authority and reports to the same.

Radio pharmaceuticals

- The Authority shall issue regulations and directives regarding the storage, distribution, use and disposal of radio pharmaceuticals in accordance with the recommendations that it may receive from the International Atomic Energy Agency.
- No person shall manufacture, import, distribute or sell radiopharmaceuticals unless he first has obtained a special permit from the Authority.

- Any person who has a special permit pursuant to this Proclamation shall keep records and send reports of manufactured, imported or distributed radiopharmaceuticals, in accordance with the directives that may be issued by the Authority.

4.10 **Principles of ethics for general public service**

The Ethiopian Pharmaceutical Association believes that these general principles for public service are directly applicable to the pharmaceutical service provision. These are the backbone of code of ethics for pharmacy professionals.

1. **Integrity**: exhibit the highest standards of professional competence and private conduct
2. **Loyalty**: dedication to upholding the constitution and the laws and trusted by fellow public officials to discharge their duties
3. **Transparency**: to be as open as possible about decisions, taking care to justify actions
4. **Confidentiality**: not to disclose information of a confidential or private nature
5. **Honesty**: keep the promises made, be sincere and be free from deceit, fraud or corruption
6. **Accountability**: be responsible for decisions and actions taken
7. **Serving Public Interest**: make decisions and act solely in the public interest and not in private interest
8. **Exercising Legitimate Authority**: power and authority should be exercised legitimately within the authority of office without any abuse
9. **Impartiality**: decisions and actions should be made in a fair and equitable manner
10. **Respecting the Law**: obey the law and comply with enactments, proclamations or directives appropriate for duties and as instructed by the relevant authority
11. **Responsiveness**: listen, respond to needs of stakeholder on time, with respect & courtesy
12. **Leadership**: promote and support these principles by taking the lead setting examples.

4.11 **Ethiopian National drug policy**

Based on economic development and the living standard of its people Ethiopia is considered to be one of the least developed countries. Although the fundamental cause is backward socio-economic system which prevailed for centuries, recent man-made and natural calamities have played a significant role in aggravating the situation. Thus, major problems which are apparent in health & pharmaceutical sectors are reflections of cumulative effects of these, state of affairs.

The most prominent and general weaknesses in the sector are that the services do not match to the needs and capabilities of the broad masses and that the limited resources allocated to the sector were not used in an appropriate, efficient and effective manner.

The Transitional Government of Ethiopia:

1. Aware of the importance of health for public welfare and productivity and the role of drugs in health care;
2. Convinced of the need for a just and equitable distribution of pharmaceutical services to all citizens and aware of the fact that to implement this goals pharmaceutical services should ensure the participation of the community based on the principles of a free market economy and in a decentralized manner throughout the regions;
3. Cognizant of the need for a strong drugs administration and regulation to maintain public health and safety, in a situation where most of the drugs are imported with possibilities of both desirable and undesirable effects;
4. Conscious of the need for a strong drugs administration and regulation to maintain public health and safety, in a situation where most of the drugs are imported with possibilities of both desirable and undesirable effects;
5. Aware of the impact of the lack of a drug policy on manufacturing, import, distribution utilization and also in the use of traditional drugs.

In this policy, DRUG means any substance or mixture of substances or medical equipments or supplies, used for human and animal health care (i.e. diagnosis, treatment, mitigation or prevention of diseases or symptoms) including poisons, narcotics and psychotropic substances chemicals, blood and blood products, vaccines, sera, radio-active Pharmaceuticals, pharmaceutical cosmetics and sanitary products.

OBJECTIVES OF THE POLICY

1. To meet the country's demand for essential drugs and to systematize its supply, its supply, distribution and use.
2. To create conducive situations to make the prices of drugs compatible with the people's purchasing power.
3. To ensure the safety, efficacy and quality of drugs.
4. To develop a domestic drug manufacturing capacity and gradual supply to the export market.
5. To expand the training of manpower and drugs research' and development.

6. To devise ways and means for the utilization of traditional drugs in the regular health services after ensuring their safety and efficacy.

General Strategies of National Drug Policy

1. Selection of drugs and drug supply
2. Stock management and distribution
3. Drug administration and control
4. Manpower training and utilization
5. Drug information and promotion
6. Trading agencies and scientific bureaus
7. Drug use and pricing
8. Traditional medicines use, research and development
9. National, regional and international relations
10. Policy enforcement

Self-check

I. Define the following terms-

- Law
- Ethics
- Professional
- Profession
- Code of ethics

II. Write the difference between Ethics & Laws

III. Say true or False

1. The pharmacy professional should not participate in the use of drugs for the purpose of euthanasia in human beings and shall refuse to participate in this practice.
2. Pharmaceutical Law is also restrictive like other Law.
3. Pharmaceutical law is needed for to ensure that the final consumers receive pharmaceuticals of proven quality, safety and efficacy.
4. Drugs can be promoted or advertising by any persons
5. Pharmacy professional should update knowledge & maintain professional competence
6. Pharmacy professional should not immediately report any observed unwanted reaction, side effects, and adverse reaction.

7. Pharmacy professional should show partiality between his/ her patients
8. Pharmacy professional should not strive for team work sprit and promotion and expansion of health service.

Summary

- ☞ Professional ethics is the moral principle, which guide members of the profession in their dealings with each, patients, the patrons, the state etc. One characteristic of members of a profession is a collective and disciplined concern of the group.
- ☞ Pharmaceutical law deals with the aspect of law and legal concepts in relation with the practice of pharmacy.
- ☞ Respecting covenantal relationship between the patient & pharmacy professional with due respect to the autonomy and dignity of each patient in order to promote the good of every patient in a caring, compassionate and confidential manner.
- ☞ The Ethical Principles and Standards in Pharmacy Practice includes:
    - Dispensing of Medications in Pharmacy
    - Compounding and Manufacturing of Pharmaceuticals
    - Pharmaceutical Supply Management and Rational Drug Use
    - Handling of Narcotic, Psychotropic and Other Dangerous Drugs
    - Quality Assurance of Pharmaceuticals
    - Promotion and Advertisement of Pharmaceuticals
    - Disposal of Unfit for Use Products
    - Pharmaceutical Regulatory Services
    - Drug Research and Development
    - Pharmacy Education
    - Pharmaceutical Care Practice
- ☞ The Ethiopian Pharmaceutical Association believes that these general principles for public service are directly applicable to the pharmaceutical service provision. These are the backbone of our code of ethics.

Critical aspects of Competence

Knowledge

- ✓ Relevant drugs and poison legislation

- ✓ Guidelines for pharmacists for the use of pharmacy support personnel
- ✓ Principles of access and equity
- ✓ Knowledge of the legal responsibilities of providers of health care in relation to confidentiality, client rights, duty of care and implications of negligence
- ✓ Principles and practices of ethical and professional conduct

Skill

- ✓ Apply pharmacy policies, procedures, standards and guidelines
- ✓ Apply legislation and regulatory requirements
- ✓ Take into account opportunities to address waste minimization, environmental responsibility and sustainable practice issues

5 Assist with prescription preparations

At the end of the chapter the learner will be able to:

- Accept prescription for dispensing
- Ensure clinical evaluation of prescription by pharmacist
- Prepare labels according to the legal requirements
- Enter data in to dispensing computer and calculate prescription quantities
- Assemble prescription items according to good dispensing practice
- Finalize prescription and documentation

5.1 Introduction to prescription processing

This topic is concerned with the assistance with preparation of prescriptions in accordance with the legal and good pharmacy practice requirements. Work performed requires a range of well-developed skills where some discretion and judgment are required. Individuals will take responsibility for their own outputs and limited responsibility for the output of others.

5.2 Accepting prescription for dispensing

The dispenser is a person who is authorized to dispense medicines and medical supplies to end users. Depending on the level of dispensaries, pharmacy professionals of varying level of qualification may be licensed for dispensing practices.

- Dispensers include:
  - Pharmacists
  - Druggists
  - Pharmacy technician

As you have learned in dispensing medication I

Prescription means:

- An important therapeutic transaction between the prescriber and medicine consumer through a dispenser.
- A written order of the prescriber for one or more medication, and instructs the dispenser how to prepare and dispense medicines and the patient how to use them.

Prescriber

- A prescriber is a health professional who makes the diagnosis and orders medicine(s) to patients. All prescribers are not at the same professional level.

Types of prescription

1. Pre-compounded prescription, prescribing readymade dosage forms
2. compounded (extemporaneous) prescription, prescribing medicines to be prepared by the dispenser as per the instruction of the prescriber

Requirements for a prescription

- Should be written on a standard prescription blank
- Should be written in ink, legible, clear, not ambiguous
- Should be written in generics, as brands could be expensive, promotional and do not give freedom to the dispenser to dispense the most affordable one.
- Should be written in English with some Latin abbreviations
- The quantity of ingredients should be expressed in metric system

Content of prescription paper

According to Guidelines for the control of use of prescription paper (Jan, 2004), published by the Food, Medicine and Health Care Administration and Control Authority (FMHACA) the content of any prescription paper should include the following information:

1. Serial number and area code.
2. Name, level and address of the health institution.
3. Full name, age, weight, sex, card number and address of the patient.
4. Type of diagnosis or International classification of disease (ICD) code number.
5. Name, strength, dosage form, treatment duration and dose of the medicine.
6. If the medicine is to be compounded, the type of ingredients needed how to prepare it, and directions on how to use it.
7. If the medicine is refillable directions for refill.
8. Prescriber's name, qualification, registration number, signature & date on which prescription is written.
9. Dispenser's name, qualification, registration number, signature and the date on which the prescription is filled.
10. Summarized directions to be followed by prescribers and dispensers.

Activity:
Dear Trainees, tries to develop standard prescription paper as legal requirements.

5.3 Collecting Prescription and Confirming

Reception

Reception is a formal party which is given to welcome someone or to celebrate a special event. As clients come into the pharmacy section, they must be made to feel attended to and comfortable by:

- ❖ Friendly gestures and smile
- ❖ Eye-to-eye contact
- ❖ A friendly welcome
- ❖ Politeness and feeling of caring

Techniques for interacting with clients at the **counter**

- ☆ Listening carefully
- ☆ Making eye contact
- ☆ Repeating what the customer said
- ☆ Using positive rather than negative words
- ☆ Language to describe what you can do
- ☆ Calling the patient by name

Client details: Full name**, a**ge, sex and weight**,** address**,** patient condition**,** diagnosis and details of medicine prescribed

Prescriber information: Full name**,** registration number**,** qualification**,** signature and date

Legality and **Validity**

A prescription is legal when:

- it is written (can also be typed) and signed by an authorized prescriber
- NPS prescription (narcotic and psychotropic prescription) for controlled drugs
- The medicines are written on the right prescription such as normal, NPS and ART
- Date of issue not exceeding 15 days for narcotic drugs and psychotropic substances and 30 days for other medicines
- Has all the information required to be contained with respect to parts of prescription

Completeness of the prescription

The prescription serves as a vehicle for communication from the licensed medical practitioner to the pharmacy professionals about the pharmaceutical care of the patient.

Details to be checked for completeness of the prescription:

- ❖ Seal of the health institution or header
- ❖ Prescriber's details
- ❖ Patient's details
- ❖ Medicine details

Checking the medicine details will include checking:

- Name of the medicine
- Dosage form
- Strength/ potency of the medicine
- Total amount to be dispensed and its availability
- Dosage and directions for use
- Frequency of administration and duration of the treatment

Reporting discrepancies to pharmacists

- o Incomplete or incorrect prescription
- o Prescription out of date
- o Prescriptions marked "cancelled" or indicate that it has been dispensed and completed
- o Prescriptions for a narcotic written by the prescriber for self-treatment
- o Questionable dosages and administration method for commonly used drugs
- o Request for excessive quantities
- o Determining cost of medication
- o Advising client of any foreseen difficulty in filling the prescription
- o Advising client of approximate waiting time and collection arrangements.
- o Checking payment and issue receipt

5.4 Clinical evaluation of prescription

1. **Identifying the patient's condition**

2. **Completeness of prescription**

a) Name of the medicine

- The name of medicine must be legible and correct without a doubt.
  - since many brands sound alike, brand confusion is quite common especially if the handwriting is illegible & pharmacy professionals proceeds on basis of guesswork.
  - prescriber should ideally write the generic name in parentheses against the brand name or write the generic name alone.
  - this makes it easier if the pharmacy professional is not familiar with the brand prescribed. It would also aid in avoiding brand confusion

Example: The prescription could state metronidazole 250 mg rather than Mezil 250 mg

Activity

Discuss amongst your colleagues the following situation:

A client comes to the pharmacy in the late evening for a prescription of

1) 'X' brand of indomethacin for severe pain & inflammation. You do not have 'X' brand stock, there is no other pharmacy close by & the prescriber is not contactable. **What do you do?**
2) 'Y' brand from a reputed multinational has been prescribed for a severe chest infection. You do not have the brand prescribed, and are not in a position to procure it for the client within 24 hours. **What do you do?**

b) Dosage form

- Some medicines are available in many different formulations.
- It is essential to check that the product on the prescription is available in the correct formulation, and to correctly choose the formulation.
- Confusion and mistakes can be made if the name of the formulation is similar to another formulation. For example, tablet formulations of a medicine are available as tablets of 25mg and 50mg, dispersible/effervescent tablets, and 100mg sustained release tablets.

The same medicine could be available as tablets, capsules, and even injections.

- important to check the prescriber's prescription for the dosage form.
- if the dosage form is not specified, it is advisable to call up the prescriber and find out, especially if the medicine is available as different formulations.

Examples, diclofenac available as 25mg, 50mg, 100mg tablets, 100mg suppository and 75m/3ml injection

c) Strength/potency of the medicine

- The pharmacy professionals should check that the strength is mentioned.
- There may be cases for prescribers to prescribe the medicine without the strength.

For example:

Paracetamol …….. Incorrect
Paracetamol 100 mg ……. Correct

If no strength is mentioned, it cannot be assumed that the lowest or highest strength has to be dispensed. This is because many times the lower strength may not be sufficient to treat the condition or higher strength may lead to toxicity. E.g. combination of amoxicillin & clavulanate (Augmentin) is available as 1gm, 625mg, 412mg, 375mg, and so on. If a lower dose is given for an adult it may not be sufficient to kill the microbial load and cure the infection.

Example, the prescriber prescribes a combination of amoxicillin and clavulanate and mentions the dose as take 5mL twice a day. It is available as amoxicillin 125mg+ clavulanic acid 31.25mg and amoxicillin 200mg+ clavulanic acid 28.5mg. In this case the pharmacy professional has to be sure about which preparation to dispense. The best option would be to consult the prescriber.

d) Quantity to be dispensed

- The prescription should lead to arrive at the exact number of the total quantity to be supplied to the patient.
- The pharmacy professional should check this quantity to confirm that it is appropriate for the patient, and that the product can be supplied in such quantity.
- For any product with a short expiry period, ensure that the quantity dispensed will not last longer than the expiry date.

Example:

If the prescription reads 'Hydrochlorothiazide 25mg tablets p.o per day for 3 months' for a chronic patient who has been taking the medicine since 3 years ago, on May 15, 2017, and the stock available of Hydrochlorothiazide in the pharmacy has an expiry date of July 2017, and no fresh stock is available, what to do? Is there a way to dispense for him all stocks? Here the patient should be politely asked to show which stock he has been taking? Thereafter, he can be advised to take 30 or 60 tablets according to the stock he has, and then to collect the balance tablets later when the pharmacy can arrange for fresh stock.

In case the duration of therapy or total quantity to be dispensed is not mentioned, it will be necessary to contact the prescriber.

e) Dosage and directions for use

- A knowledgeable and an alert pharmacy professional can be a great asset and a lifesaver especially if the prescriber makes mistakes (at times major ones) while prescribing.

f) Contraindications

- The age, sex, disease(s) conditions, or other characteristics of a patient may cause certain prescribed medicines to be contraindicated. The pharmacy professional should look out for such contraindications.
- The dose should always be checked taking into account the patient's age, and weight (especially for a child or for the elderly and pregnant woman).
- For pregnant woman all categories, A, B, C, D and X should be checked; i.e.

Medicines under category 'A'

- Adequate well controlled studies in pregnant woman do not show risk to the fetus example vitamins like B complex, minerals like iron.

Medicines under category 'B '

- Either animal findings show risk and human findings do not, or, if no adequate human studies have been done, animal findings do not show risk. Example like ceftriaxone sodium injection, chlorpheniramine maleate

Medicines under category 'C'

- Human studies are lacking, and animal studies either show risk or lacking as well. However, potential benefits may out way the potential risks.
- Example: albendazole, aspirin with codeine phosphate.

Medicines under category 'D'

★ Investigational or post marketing data show risk to the fetus .nevertheless, the potential benefits may sometimes outweigh the risk.

★ Example: Atenolol, captopril, phenobarbitals

Medicines under category 'X'

- Studies in animals or humans or investigational or post marketing surveillance reports show fetal risk that clearly outweighs possible benefits gained from drug to the patient.
- Example ethinylestradiol and norethindrone, lovastatin, simvastatin, thalidomide, vitamin A, warfarin sodium.

More examples:

- Aspirin is not recommended for children <12 years age; so caution should be taken.
- Atenolol is contraindicated in asthma.

➢ The pharmacy professional should always check that the dose, dosage regimen and any directions for use are appropriate for the patient and the medicine.

➢ Any suspected medicine under dose/overdoses or inappropriate dosing should always be referred to the prescriber.

➢ The dose should be carefully checked in case of children, and for all categories of potent medicines. Confirm the units written on the prescription, i.e. milligrams, micrograms, decimal points, etc. for medicines like digoxin.

Example:

You need to check carefully whether the prescription states:

0.25 mg or 0.025 mg.

0.5mg or 50mg

0.125mg or 125mcg (microgram)

- The pharmacy professional should verify, whether the dosage prescribed is within the standard minimum and maximum dose range. Use standard textbooks or reference books for the standard dose.
- Develop a professional and good relationship with prescribers in the vicinity of the pharmacy or with those whose prescriptions come to you, so that you feel confident and not afraid to talk/discuss with the prescriber about a possible prescribing error.

g) Frequency of administration

- Check if the frequency recommended by prescriber is as per the standard dosing patterns.
- Doses more frequent than standard, proven doses may cause toxic manifestations.
- At the same time, doses lesser than standard, required doses may result in failure to treat the condition properly.
- In addition to frequency of administration, adherence to the time schedule is also important. For instance, patients taking medicines for hypertension have to take the medicine at the same time to maintain blood levels of the medicine.

3. **Correctness of the prescription**

a) Checking double medication

- Same medicine or different medicine with same pharmacotherapeutic effect concurrently prescribed by the same or different prescribers to the same patient undergoing treatment.

> **Example**: If a patient has been prescribed diclofenac for fever, and if the dentist has prescribed other NSAIDs for the same patient, it could lead to overdosing of NSAIDs, and result in the risk of GI bleeding and may aggravate hypertension.

b) Interactions

- Many medicines are known to interact with other prescribed or OTC medicines, food, diseases, herbal medicines, and laboratory results.
- Ideally, all multiple item prescriptions should be checked for medicine interactions. (Unfortunately, checking for medicine interactions is a major problem in Ethiopia because of the large number of medicines prescribed by prescribers.
- If a prescribed item is known to interact with many medicines or to interact with OTC medicines then it is imperative that the pharmacy professionals check with the patient which other medicines or traditional/complementary medicines the patient is taking, in order to eliminate possible medicines interactions
- Any medicine interactions likely to render the therapy ineffective or cause undesirable effects to the patient, or affect the treatment in any way, should be brought to the notice of the prescribing prescriber (without unduly alarming patient).

☞ **Tips for Managing Drug Interactions**

1. Using relevant and updated references or checklist
2. Consistently following the 6 steps of dispensing
3. Ask the patient what additional drugs he/she is taking(using) at home
   - On OTC basis
   - On Prescription only basis (POM)
   - Herbal or traditional medicines
   - Recreational drugs
4. Assessing if the current medications on the prescription interact with each other or with those mentioned in no 3.
5. Determine the type of interaction
   - (Pharmacokinetic or Pharmacodynamics; drug –drug, or drug – food, or drug – laboratory value, drug- disease interactions)
6. Ruling out whether the interaction is significance or not; with emphasis given to the significant types
7. If the drugs interact, listing all the possible consequences of the interaction
   - Enhanced toxicity
   - Therapeutic failure including drug resistance
   - Beneficial effect etc.
8. Recognizing the interaction /s/ by assessing sign and symptoms of the interaction
9. Management of the interaction
   - ★ Timing between doses of each interacting drugs or foods
   - ★ Dose adjustment
   - ★ Switching to/substitute with safer alternative
   - ★ Effective counseling, etc…
10. Documentation and Reporting of drug interactions

c) History of overuse, under use or misuse of medicines by the patient.

d) Check for overwriting

- Overwriting can be done by the patient, to buy extra medicines (especially habit forming medicines or medicines of abuse).

e) Fake/false prescription

- Pharmacy professionals should be alert to detect misuse of prescription blanks by clients (obtained by stealing from private practitioners or from Government hospital OPDs, where blanks are often left lying around).
- Pharmacy professionals should also be alert to fake prescriptions written/printed by the patient or client coming to the pharmacy. If the handwriting is not the usual handwriting of the prescriber or you notice it to be unusual otherwise, confirm with a senior colleague or call the prescriber to confirm.
- Do not dispense such prescriptions & be sure to alert the prescriber about the misuse.

f) For potent medicines, and medicines with a narrow therapeutic index

- Special care has to be taken with such medicines, as slight changes in systemic concentration lead to marked changes in pharmacodynamic responses.
- E.g., of narrow therapeutic index medicines: digoxin, lithium, phenytoin, warfarin

g) **Special care has to be taken in case of**:

- Medicines with similar names
- Abbreviations

h) Changes to the prescription

- Before a pharmacy professional attempts to dispense a prescription, he/she must read and understand it thoroughly.
- If any portion of prescription is not understood, or has detected an incompatibility, he/she should consult pharmacist/ the prescriber who wrote the prescription.
- Any changes made to the prescription over the telephone by the prescriber, should be recorded on the prescription, with the words "changes made over the telephone, in consultation with the prescriber at (time) on (date)" and should be signed and stamped by the pharmacy professional. This exercise facilitates a trust based professional relationship with the prescriber, besides documenting the changes made to the legal document - the prescription, by the pharmacy professional.
- Many pharmacy professionals hesitate to call the prescriber about these matters, but, if the calls are executed tactfully, there is no reason why they should not create a better understanding between the persons of both professions.

4. **Therapeutic aspects**

a) **the safety of the medicine**

- Choosing effective group of medicines according to efficacy, safety, suitability and cost of treatment.

Example:

- The benefit of adding digoxin to a diuretic and vasodilator **counterpart** the risk of its toxicity in the treatment of congestive cardiac failure. This might depend on the cause of the heart failure, patient compliance, renal function and ease of monitoring of plasma digoxin concentration.
- The benefit from a course of antibiotic in treating urinary tract infection in two months pregnant as compared to the risk of treatment to the fetus. Here the risk of teratogenesis needs to be compared to the risk of renal damage to the mother as a result of untreated infection.

b) **possible contra-indications:** e.g., avoid aspirin in a patient on warfarin treatment

c) drug/drug interactions

d) drug/food interaction

e) drug/disease interactions, and

f) Treatment duplications.

5. **Appropriateness of the individual**

- Confirm that the dose and duration of prescribed medicine are in the normal range for the patient (noting sex and age or weight)
- NB. Under no circumstances should an untrained person attempt to read or discuss the prescription with the client.

5.5 Prepare Labels for Dispensed Medications

Definition of Labels

- Label is a slip of paper or other material, marked or inscribed, for attachment to medicines to indicate its manufacturer, nature, ownership, destination, etc.
- The prescription label provides information to the patient regarding the dispensed medication and how to take it.
- Additionally, the label includes information about the pharmacy, the patient, the prescriber, and the prescription or transaction number assigned to the prescription.

Reason for having labels

- indicate clearly the contents of the container
- indicate clearly to patients how & when medicinal product should be taken or used
- indicate clearly to patients how the product should be stored and for how long
- indicate clearly to patients any warnings or cautions need to be made aware.

Contents of label

- Minimum drug label information should include the following:
  - Patient name
  - Generic name, strength and dosage form of the medicine
  - Dose, Frequency and Duration of use of the medicines
  - Quantity of the medicine dispensed
  - How to take or administer the medicine?
  - Storage condition
  - For extemporaneous preparations a batch number may be included.

☞ All labels must be unambiguous, legible, accurate and comprehensible.

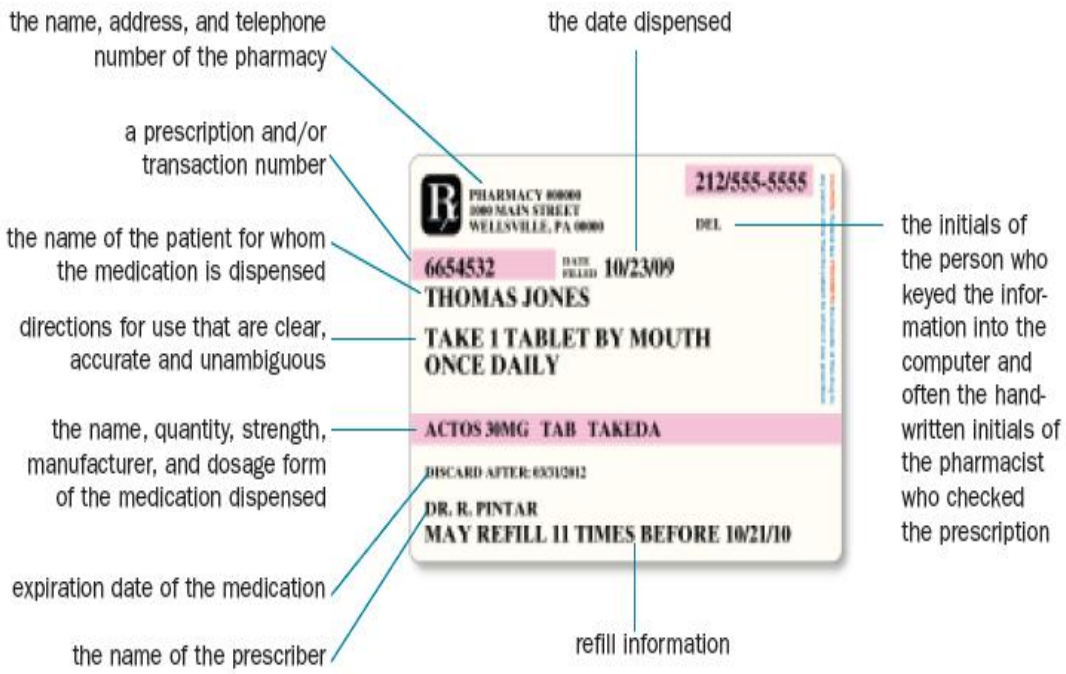

the name, address, and telephone number of the pharmacy
the date dispensed
a prescription and/or transaction number
the name of the patient for whom the medication is dispensed
directions for use that are clear, accurate and unambiguous
the name, quantity, strength, manufacturer, and dosage form of the medication dispensed
expiration date of the medication
the name of the prescriber
refill information
the initials of the person who keyed the information into the computer and often the hand-written initials of the pharmacist who checked the prescription
PHARMACY 00000
0000 MAIN STREET
WELLSVILLE, PA 00000
212/555-5555
DEL
6654532
DATE FILLED 10/23/09
THOMAS JONES
TAKE 1 TABLET BY MOUTH ONCE DAILY
ACTOS 30MG TAB TAKEDA
DISCARD AFTER: 03/31/2012
DR. R. PINTAR
MAY REFILL 11 TIMES BEFORE 10/21/10

Figure 4-1: Contents of medication labels

Direction for use

- ☞ **Directions should start with a verb** (take, instill, inhale, insert, apply) and completely, clearly, and accurately describe the administration of the medication.
- ☞ **Indicate the route of administration**. E.g., 'take one capsule by mouth,' 'apply to affected area,' 'insert rectally,' 'place one tablet under the tongue,' etc.
- ☞ **Use whole words, not abbreviations**. E.g., use 'tablets' not 'tabs.'
- ☞ **Use familiar words, especially in measurements**. E.g., use 'two teaspoonful' or '10 mL' as most measuring droppers and spoons are calibrated in teaspoons and mL.
- ☞ **Double check** that the units listed on the label match the units on the measuring spoon or dropper supplied

Auxiliary labels

- ✓ Colored auxiliary labels may be applied to the prescription container to provide additional information to the patient (Shake Well, Keep Refrigerated, Take with Food).
- ✓ Many computerized prescription systems will automatically print out the appropriate labels to use.

Examples of auxiliary labels

- TAKE WITH FOOD
- MAY CAUSE DROWSINESS
- DONOT DRINK ALCOHOL BEVERAGES WHEN TAKING THIS MEDICINE
- TAKE MEDICATION ON EMPTY STOMACH
- THIS DRUG MAY IMPAIR YOUR ABILITY TO DRIVE OR OPERATE MACHINERY
- FOR EXTERNAL USE ONLY
- AVOID PROLOGED EXPOSURE TO SUNLIGHT WHILE TAKING THIS MEDICINE

PLACING THE LABEL

Be Healthy Pharmacy
555-1234 1 Main St Well City PA
DEA No. 1111119 Dr. Smith
Ben Arnold No. 339162
TETRACYCLINE 250 mg
TAKE ONE CAPSULE FOUR TIMES A DAY UNTIL ALL ARE GONE
Date Filled: 1/7/10
SPECIAL INSTRUCTIONS

Labeling the container correctly includes:

- ✔ placing the computer-generated label on the container so it is parallel to the edges of the container, easy to locate, and easy to read;
- ✔ making sure the label sticks adequately to the container and is without creases. (Some pharmacies place transparent tape over the label to protect the label from spills and prevent accidental smudging.);
- ✔ placing the appropriate auxiliary labels on the container;
- ✔ placing labels on prescription vials containing eye drops, ear drops and eye ointments;
- ✔ in some states, placing the label on the actual container rather than the box in which it is packaged.

Figure 4-2: Placing labels on containers

Labels Characteristics

1. **Legible**
    - Always check label print size and quality to ensure that it can be read clearly.
    - If there is too much information to place on one label, consider placing the additional information on a secondary label, rather than reducing the size of the print or trying to include too much information on one label.
2. **Concise**
    - Although it is important that sufficient information is placed on the label, it must be remembered that it is important not to confuse the patient by placing too much information on the label.
    - If the label contains too much information, rather than assisting patients, they may feel overwhelmed and as a result they may read none of the information.
3. **Adequate**
    - Ensure that sufficient information is given. For example, the term 'when required' raises the questions how much? How often? When required for what?
4. **Accurate**
    - It is important that the title is accurate, the instructions are accurate and that the patient name is complete and accurate.

Activity: Dear trainees, tries to develop format of label for medicine according to the legal requirements**.**

5.6 Enter data into dispensing computer

Pharmacy computer system

There are many different kinds of computer systems in retail and hospital pharmacy. Among the many available options, these systems can:-

- Automate the printing of the label
- Coordinate billing and pricing with insurance
- Use bar codes to check medication identification when filling prescriptions
- Check for allergies and possible drug interactions

- Print medication information for the patient and
- In some hospital systems also calculate weight-based dosing and provide disease-specific alerts based on lab values, provide drug information for the pharmacists and nurses, automate filling prescriptions and medication orders and managing inventory.

- **Computerized inventory systems automatically adjust inventory and generate orders based on maintaining set inventory levels.**
- The inventory system is often a component of a comprehensive pharmacy management system that includes elements like patient profiling, management reporting, and so on.
- In many cases, the drug wholesaler provides the system to its customers as part of the wholesaler service. The customer's system interacts with the wholesaler's so that various types of information (pricing, order information, etc.) can be exchanged automatically between the two systems.
- Entering correct information is essential to any computer system.
- To protect against possible abuses, users are given passwords to access different features.

System Care and Maintenance

- Computer systems have become very durable, but they need care and maintenance.
- It is important to know and follow the operating instructions for any system.
- Some factors that can cause damage to computers are temperature, dust, moisture, movement, vibrations, and power surges.

System Backup

- Each system's database of information is a critical component of the pharmacy or institution in which it functions.
- These files must be regularly backed-up or copied to an appropriate storage media.
- Depending on the operation, back up may need to be performed daily.

Manual Checking

- Checking reports manually is an important step in ensuring that records are correct.
- Simple data entry errors can result in serious mistakes affecting orders, stock availability, prices, and other issues.
- For example: If a box containing 150 u/d tablets of Tylenol® is set up in the system as one unit, but is incorrectly keyed into the system as 150 units, the system's information will be grossly incorrect.

Automated dispensing systems

- Is a system in which medications are dispensed, upon confirmation of an order communicated from a centralized computer system, at their point-of-use.
- **Database** a collection of information structured so that specific information within it can easily be retrieved and used.
- Ordering systems involve automated and manual activities. Much of the work is done by computer systems.
- However, manual checking, editing, and confirmation are essential to making such systems work as required.

- The patient healthcare record should be created or updated in the pharmacy dispensing software at time of dispensing, and the information confirmed as correct.
- At the time of dispensing, the pharmacy dispensing software is used to:
  - record the details of all prescriptions dispensed
  - record any other legally required details of dispensing
  - generate a dispensing label
  - generate a repeat authorization to attach to the duplicate of the prescription

The patient healthcare record may include:

- patient details (e.g. date of birth)
- medical history, including medical conditions, allergies & details of adverse reactions
- medicines the patient is taking, including OTC and complementary medicines
- details of any recent medication changes
- relevant patient notes including brand preferences, details of services provided, communication with prescriber, reasons for early or multiple repeats supplied, and follow-up actions required

- Pharmacists should ensure that the patient's healthcare record is consistent and integrates with the patient's national digital health record, where appropriate.

5.7 Calculate prescription quantities

Proper dosing of medications is important to ensure patient safety. Calculating dosages, dosage regimens, and compounding formulas involves the use of simple math principles. You can solve

many of these problems by setting up ratios and proportions using the information given in the question and keeping like units consistent.

In order to calculate quantity and day supply, it is important to understand unit of measure and Latin abbreviations used on prescriptions. A review of unit of measure abbreviations and Latin abbreviations are beyond the scope of this module. Readers are encouraged to refer to the dispensing medicine module I and pharmaceutical science module.

Definition of Doses:

The dose of a drug is the quantitative amount administered or taken by a patient for the intended medicinal effect. The dose may be expressed as a single dose, the amount taken at one time; a daily dose; or a total dose, the amount taken during the course of therapy.

A daily dose may be subdivided and taken in divided doses, two or more times per day depending on the characteristics of the drug and the illness. The schedule of dosing (e.g., four times per day for 10 days) is referred to as the dosage regimen.

Dosage Calculations

Dosage calculations include calculating the number of doses, dispensing quantities, and ingredient quantities; these calculations are performed in the pharmacy on a daily basis. The pharmacy technician must have a full working knowledge of how to perform these calculations.

To perform dosage calculations, you will utilize the information and principles introduced in pharmaceutical science module I. You can solve these calculations by setting up ratios and proportions, keeping like units consistent, and cross-multiplying.

The dose of a drug is based on:

- biochemical and pharmacologic activity
- physical and chemical properties
- the dosage form used
- the route of administration, and
- various patient factors

Calculating the number of doses

To calculate the number of doses, you should first determine which information presented is actually applicable to the question. Too often mistakes are made on dosage calculations because we overcomplicate them.

Dose Measurement

In the institutional setting, doses are measured and administered by professional and paraprofessional personnel.

In the home setting, the adult patient or a child's parent generally measures and administers medication. Exceptions occur when home health care personnel are involved in a patient's care.

Liquid dosage is usually measured in ''household'' terms, most commonly by the teaspoonful and tablespoonful. An oral dispenser finds use in administering calibrated quantities of liquid medication to children. For calculating dosages, useful equivalent measures are provided.

Teaspoon and Tablespoon

In calculating doses, pharmacy personnel and physicians accept a capacity of 5 mL for the teaspoonful and 15 mL for the tablespoonful. It should be noted that the capacities of household teaspoons may vary from 3 to 7 mL and those of tablespoons may vary from 15 to 22 mL. Such factors as viscosity and surface tension of a given liquid, as well as the technique of the person measuring the liquid, can influence the actual volume held by a household spoon.

Table: Useful approximate equivalent of household measure

1 Teaspoonful = 5 mL
1 Tablespoonful = 15 mL
1 Tea cupful = 120 mL
A wine glassful = 60 mL
A tumblerful = 240 mL (1 full glass)

The Drop as a Unit of Measure

The drop (abbreviated gtt) is used as a measure for small volumes of liquid medications. A drop does not represent a definite quantity, because drops of different liquids vary greatly. In an attempt to standardize the drop as a unit of volume, the United States Pharmacopeia defines the official medicine dropper as being constricted at the delivery end to a round opening with an external diameter of about 3 mm.

The dropper, when held vertically, delivers water in drops, each of which weighs between 45 and 55 mg. accordingly, the official dropper is calibrated to deliver approximately 20 drops of water per milliliter (i.e., 1 mL of water 1 gram or 1000 mg ÷ 50 mg /drop = 20 drops).

It should be kept in mind that few medicinal liquids have the same surface and flow characteristics as water, and therefore the size of drops varies materially from one liquid to another. The drop should not be used as a measure for a specific liquid medication until the volume that the drop represents has been determined for that liquid. This determination is made by calibrating the dispensing dropper. The calibrated dropper is the only one that should be used for the measurement of medicine.

A dropper is calibrated by counting the drops of a liquid as they fall into a graduate until a measurable volume is obtained. The number of drops per unit volume is then established.

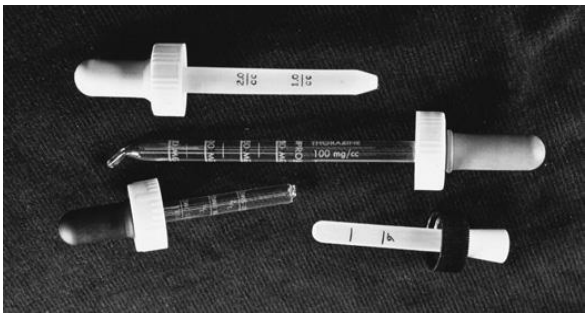


FIGURE: Calibrated droppers used in the administration of pediatric medications

Example: If a pharmacy professional counted 40 drops of a medication in filling a graduate cylinder to the 2.5-mL mark, how many drops per milliliter did the dropper deliver?

$$\frac{40\ (drops)(drops)}{X} = \frac{2.5\ (mL)}{1\ (mL)}$$

X = 16 drops per mL, answer.

Exercise: A physician asks a pharmacist to calculate the dose of a cough syrup so that it may be safely administered drop wise to a child. The cough syrup contains the active ingredient dextromethorphan HBr, 30mg/15 mL, in a 120 mL bottle. Based on the child's weight and literature references, the pharmacist determines the dose of dextromethorphan HBr to be 1.5 mg for the child. Calculate the dose of the syrup for the child in drops

General Dose Calculations

A pharmacist often needs to calculate the size of a dose, the number of doses, or the total quantity of medication to dispense. For these calculations the following equation is useful with the terms

rearranged depending on the answer required. In using the equation, the units of weight or volume must be the same for the total quantity and size of the dose.

$$Number\ of\ doses\ = \frac{Total\ quantity}{Size\ of\ dose}$$

Example Calculations of the Number of Doses

1. If the dose of a drug is 200 mg, how many doses are contained in 10 g?

10 g = 10,000 mg

$$Number\ of\ doses = \frac{10,000\ (mg)}{200(\ mg)}\ \ = \mathbf{50\ doses}$$

Or, Solving by dimensional analysis:

$$\frac{1dose}{200mg}x\ \frac{1000mg}{1g}x\ 10g = \mathbf{50\ doses}$$

2. If the dose of a drug is 50 µg, how many doses are contained in 0.020 g?

0.20 = 20 mg

0.020g=20mg

50µg= 0.05mg

$$Number\ of\ doses = \frac{20mg}{0.05mg}\ \ = \mathbf{400\ doses}$$

Example Calculations of the Size of a Dose

$$Size\ of\ doses = \frac{Total\ quantity}{Number\ of\ doses}$$

The size of the dose is expressed in whatever denomination is chosen for measuring the given total quantity.

1. How many teaspoonful would be prescribed in each dose of an elixir if 180 mL contained 18 doses?

$$Size\ of\ doses = \frac{180ml}{18\ doses} = \mathbf{2\ teaspoonfuls(10ml)}$$

2. How many drops would be prescribed in each dose of a liquid medicine if 15 mL contained 60 doses? The dispensing dropper calibrates 32 drops/ml.

15 mL= 15 x 32 drops = 480 drops, $Size\ of\ doses = \frac{480(\ drops)}{60}$ = ***8 drops***

Example Calculations of the Total Quantity of Product

Total quantity = Number of doses x Size of dose

It is convenient first to convert the given dose to the denomination in which the total quantity is to be expressed.

1. How many milliliters of a liquid medicine would provide a patient with 2 tablespoonfuls twice a day for 8 days?

   Number of doses = 16

   Size of dose = 2 tablespoonful or 30 mL

   Total quantity =16 x 30 mL = ***480 mL***

2. How many milliliters of a mixture would provide a patient with a teaspoonful dose to be taken three times a day for 16 days?

   Number of tsp doses = 16 x 3 = 48 tsp

   Total quantity = 48 x 5 mL = 240 mL

3. How many grams will be needed to prepare 72 dosage forms if each is to contain 30 mg?

   Number of doses = 72

   Size of dose = 30 mg

   Total quantity = 72 x 30 mg = 2160 mg = 2.16 g

4. It takes approximately 4 g of ointment to cover an adult patient's leg. If a physician prescribes an ointment for a patient with total leg eczema to be applied twice a day for 1 week, which of the following product sizes should be dispensed: 15 g, 30 g, or 60 g?

   Number of doses = 2 per day x 7 days = 14

   Size of dose = 4 g

   Total quantity =14 x 4 g = 56 g; thus, 60 g product size

Splitting Tablets

- A number of tablets are scored, or grooved, to allow breaking into approximately equal pieces (usually halves). This allows dosage flexibility, particularly when a patient is started at a half dose and then is titrated up to a full dosage level. It also enables a patient to take a product at a strength that is not otherwise available.
- Patients use tablet-splitting devices to cut scored or unscored tablets for economic reason.
- For some medications, the price of tablets of twice the strength required is similar to the lower-strength tablets, and the patients can double his or her supply by tablet splitting.
  - this practice often results in unequal portions of tablets, thus uneven doses.

- Additionally, patients may not be aware that many solid dosage forms should not be cut or crushed but must remain intact for proper drug absorption. However, for tablets that can be crushed without destroying desired absorption characteristics, tablet crushing is a commonly employed practice for home- or institutional-patients who are unable to swallow intact solid dosage forms. In these instances, mortars and pestles or specially designed tablet crushers are used. After crushing, the resulting particles may be suspended in a beverage or mixed with a foodstuff as yogurt prior to administration.

Calculating the quantity of doses

- ☞ Always use the higher dosage amount when performing dosage calculations on prescriptions that have a range for the dose. This will provide the most conservative solution and ensure the most accurate potential for days' supply.
- ☞ To calculate the appropriate quantity to dispense, use the following formula:

Quantity to dispense = Dose x Frequency x Duration of treatment

Example:

1. How many tablets are provided in the prescription below?

   Phenobarbitone on hand 15mg tablet

   R_x - Phenobarbitone 30mg tablet po BID for 30 days

   15mg = 1tablet

   Dose = 1 tablet

   Frequency = BID= every twelve hours= 2 tablet

   Duration = 30 days

   Quantity to dispense = Dose x Frequency x duration

   = 1x2x30 = 60 tablets

   Therefore, the quantity to dispense is, 60 tablets

2. R_x - Penicillin G, Crystalline sodium 3 MIU IV, QID, for 7 days

   Hint: 1 vial of Crystalline sodium injection = 1 MIU

   Calculate the quantity you dispense for this patient?

   Vial = 1 MIU

   Dose = 3 MIU

   Frequency = Every six hours= 4

Duration = 7 days

Quantity to dispense = Dose x Frequency x Duration

= 3 x 4 x 7 = 84 vials

Exercises:

1. How many capsules, each containing a 150-mcg dose of a drug may be prepared from 0.12 g of the drug?
2. The following regimen for oral prednisone is prescribed for a patient: 50 mg/ day x 10 days; 25 mg/day x 10 days; 12.5 mg/day x10 days; 5 mg/day x 10 weeks. How many scored 25-mg tablets and how many 5-mg tablets should be dispensed to meet the dosing requirements?
3. You receive a prescription for phenindione tablets 50 mg with the following instructions: '200 mg on day 1, 100 mg on day 2, then 50 mg daily thereafter'. Mitte: 56 days' supply.
4. If a liquid medicine is to be taken three times daily, and if 180 mL are to be taken in 4 days, how many tablespoonful should be prescribed for each dose?
5. What quantity should be dispensed if 50 mg of amitriptyline has been prescribed daily for 3 weeks, if the medication on your hand is 25mg?
6. A prescription was written for 750mg dose of drug X to be taken 3 times a day for 10 days. There are 500mg of drug X in 1 tablet. How many tablets should be dispensed for a 10-day supply?
7. A prescription is written for the patient to take 2 tablets Q 8 hours. The prescription calls for 180 tablets to be dispensed. How long with this prescription last? Calculate the day's supply.

Calculation of Parenteral Doses

Drugs for parenteral use must be in liquid form before they are administered. Parenteral drugs may be available in the following forms:

1. **As liquids in disposable cartridges or disposable syringes:**
   - that contain a specific amount of a drug in a specific volume, for example, meperidine 50 mg/ mL. After administration, the cartridge or syringe is discarded.
2. **In ampules or vials**
   - That contains a specific amount of the liquid form of the drug in a specific volume.
   - The vials may be single-dose vials or multi-dose vials.

- A multidose vial contains more than one dose of the drug.

3. In ampules or vials that contain powder or crystals

- To which a liquid (called a diluent) must be added before the drug can be removed from the vial and administered.
- Vials may be single dose or multidose vials.

Example Calculations of Measures of Activity or Potency

Determinations of the activity or potency of a biologic material considered in this chapter may be performed through the use of ratio and proportion or dimensional analysis, as demonstrated by the following examples.

Calculations involving units of activity are exemplified as follows.

Example:

1. How many milliliters of U-100 insulin should be used to obtain 40 units of insulin? U-100 insulin contains 100 units/mL

$$\frac{100(units)}{40(units)} = \frac{1(ml)}{x(ml)} \quad = 0.4ml$$

2. A physician prescribed 100 units of insulin to be added to 500 mL of D5W in treating a patient with severe diabetic acidosis. How many milliliters of insulin injection concentrate, U-500, should be used? U-500 insulin contains 500 units/mL

$$\frac{100(units)}{100(units)} = \frac{1(ml)}{x(ml)} \quad = \ 0.2ml$$

3. How many milliliters of a heparin sodium injection containing 200,000 units in 10 mL should be used to obtain 5,000 Heparin Sodium Units that are to be added to an intravenous dextrose solution?

$$\frac{200{,}000(units)}{500(units)} = \frac{10(ml)}{X(ml)} \quad = 0.25\ ml$$

4. Rx- Lente Insulin 30IU a.m /20IU p.m for 60 days. How many vials you dispense for this patient? Hint: U-100 insulin contains 100 units/mL

   Vial = 10mL

   Dose=30 IU + 20 IU = 50 IU

   Duration= 60 days

   Vial to dispense= 50 IU x 60 days= 3000 IU

   Therefore, 1000IU = 1vial

3000 IU = X

X= 3 vials

5. Rx- Fortified Procaine Penicillin (PPF) 800,000 IU/day for 7 days.
   How many vials you dispense for this patient? (1 vial = 4,000,000IU)
   First calculate the dose = 1vial=10ml= 4000000IU
   By dimensional analysis,

$$\frac{800000}{4000000} = \frac{X\ (mL)}{10\ (mL)} = 2\ mL$$

   Quantity in mL = 2 mL x 1x 7= 14Ml, Vial to dispense = 2 vials

Rate of Flow of Intravenous Fluids

On medication orders, the physician specifies the rate of flow of intravenous fluids in milliliters per minute, drops per minute, amount of drug (as milligrams per hour), or, more frequently, as the approximate duration of time of administration of the total volume of the infusion. Pharmacy professional may be called on to perform or check rate-of-flow calculations as those described in the following example problems in this section.

$$Flow\ rate(drop/\ minute) = \frac{Drops\ per\ ml\ of\ \ given\ set(drop\ factor)}{60(minute\ in\ hour)}\ x\ total\ hourly\ volume$$

Example: 3L of D5W is to be infused over 24 hours, using an IV set that delivers 15gtt/ml. Calculate the flow rate?

$$\frac{Drops}{min} = \frac{\frac{3000ml}{1440min}x15gtt}{ml}$$=31.25gtt/min or 31 drops/min

Exercise:

1. How many milliliters of U-100 insulin zinc suspension is used to obtain 18 units of insulin?
2. The physician orders Ferrous Sulfate 500 mg po qd x 30 days. You have on the shelf Ferrous Sulfate 220 mg/5 ml 473 ml. How many ml is required for one dose?
3. Using the information from question No 2, approximately how many ml are required to completely fill this prescription?
4. A medication order calls for 1000 mL of D5W to be administered over an 8-hour period. Using an IV administration set that delivers 10 drops/mL, how many drops per minute should be delivered to the patient?

5. Ten (10) milliliters of 10% calcium gluconate injection and 10 mL of multivitamin infusion are mixed with 500 mL of a 5% dextrose injection. The infusion is to be administered over 5 hours. If the dropper in the venoclysis set calibrates 15 drops/mL, at what rate, in drops per minute, should the flow be adjusted to administer the infusion over the desired time interval?
6. The infusion rate of an IV is over twelve hours. The total volume is 1000 ml. What would the infusion rate be in ml per minute?
7. If the dose of a drug is 500 mg and the drug is available as 400 mg/5 ml, how many teaspoonful are needed for the required dose?
8. Describe why proper dosing of medications is important to ensure patient safety

Calculation of Pediatric Doses

Pediatrics is the branch of medicine that deals with disease in children from birth through adolescence. Because of the range in age and bodily development in this patient population, the inclusive groups are defined further as follows:

- Neonate (newborn) - from birth to 1 month
- Infant - 1 month to 1 year
- Early childhood - 1 year through 5 years
- late childhood- 6 years through 12 years and
- Adolescence 13 years through 17 years of age

➢ The dose of a drug for a particular patient may be determined in part on the basis of the patient's age, eight, body surface area, general physical health, liver and kidney function (for drug metabolism and elimination), and severity of the illness being treated

Drug Dosage Based on Age

The age of the patient is a consideration in the determination of drug dosage. As stated previously, neonates have immature hepatic and renal functions that affect drug response. The elderly, in addition to diminished organ function, frequently have issues of concomitant pathologies and increased sensitivities to drugs.

Young's Rule

$$Dose\ for\ child = \frac{Age}{age + 12} x\ Adult\ dose$$

Example:

If the adult dose of a drug is 5mg.What is the dose for a child 8 years old?

$$Dose\ of\ child = \frac{8}{8+12} x5mg = 2mg$$

Cowling's rule

$$Dose\ for\ child = \frac{Age\ at\ next\ birthday(in\ years)}{24} x\ Adult\ dose$$

Fried's Rule for infants

$$Dose\ for\ child = \frac{Age\ (in\ months)}{150} X\ Adult\ dose$$

Note: The value of 150 in Fried's rule was an estimate of the age (12.5 years or 150 months) of an individual who would normally receive an adult dose, and the number 150 in Clark's rule was an estimate of the weight of an individual who likewise would receive an adult dose.

Drug Dosage on Body Weight

Clark's Rule

$$Dose\ for\ child \quad = \quad \frac{Weight(in\ lb)xAdult\ dose}{150(average\ weight\ of\ adult\ in\ lb)}$$

Example:

The usual initial dose of chlorambucil is 150 mcg/kg of body weight. How many milligrams should be administered to a person weighing 154 lb.?

Solving by the equation: 454g= 2.2lb

150 mcg = 0.15 mg

Patient's dose (mg) $= 154\ lb\ x \frac{0.15mg}{2.2\ lb}$ = 10.5mg of chlorambucil

Drug Dosage Based on Body Surface Area

The body surface area (BSA) method of calculating drug doses is widely used for two types of patient groups: cancer patients receiving chemotherapy and pediatric patients, with the general exception of neonates, who are usually dosed on a weight basis with consideration of age and a variety of biochemical, physiologic, functional, pathologic, and immunologic factors.

The average adult is considered to have a BSA of 1.73 m2.

A useful equation for the calculation of dose based on BSA is:

$$Patient's\ Dose = \frac{Patient's\ BSA(\ m^2)}{1.73\ m^2}\ X\ Drug\ dose(mg)$$

Example:

If the adult dose of a drug is 100 mg, calculate the approximate dose for a child with a BSA of 0.83 m2?

$$Child'sdose = \frac{0.83m^2}{1.73m^2}\ x\ 100mg = 47.97mg\ or\ 48mg$$

Exercise:

1. If the adult dose of a drug is 0.1ml, what is the dose for 12 years old child?
2. The usual dose of atropine sulphate is 0.5mg. Calculate the dose for infant six month old?
3. The usual dose of sulfisoxazole for infants over 2 months of age and children is 60 to 75 mg/kg of body weight. What would be the usual range for a child weighing 44 lb.?
4. A hospital pharmacy assistant is called to a pediatric nursing station to calculate the quantity of an injection to administer to a pediatric patient. The daily dose of the injection for the child's weight is stated as 15 mg/kg/day, divided into three equal portions. The child weighs 10 kg. The injection contains 5 mg/mL of the prescribed drug. How many milliliters of injection should be administered?
5. If the loading dose of Kanamycin is 7 mg/kg of body weight. How many grams should be administered to a patient weighing 130 lbs.?
6. If the adult dose of a drug is 75 mg, what would be the dose for a child weighing 40 lb. and measuring 32 inch in height using the BSA nomogram?(BSA =0.060m^2)

5.8 **Assembling prescriptions items**

Packaging of **medicines** is the process of enclosing a product or production process

Figure 4-3 Packaging of dispensed medication

Medicines must be suitably contained, protected and labeled from the time of manufacture until they are used by the patient. The container must maintain the quality, safety and stability of the medicine throughout this period.

Purpose of Packaging:

- Physical and barrier protection
- Containment and security
- Information transmission
- Convenience
- Offer consumer safety

The selection of packaging for medicines depends on:

- Nature of the medicine
- Type of patient and dosage form
- Method of administering the medicine
- Required shelf-life
- Use, such as for dispensing.

☞ Original containers used by manufacturers are expected to protect medicines for their specified shelf-life. Because original containers may contain large amount of medicines, repackaging of medicines into another container may be necessary in order to dispense medicines for patients. Such repackaging procedure can be done at-the –spot or in advance.

Prepackaging

- Prepackaging is the process by which the pharmacy professional transfers a medication manually from a manufacturer's original commercial container to another type of container in advance (before clients come to medicine retail out lets).

The following guidelines are recommended in prepackaging of medicines:

- Prepackaging procedures must comply with laws and regulations.
- Prepackaging operations & area must be separate from other pharmacy activities.
- Only one medicine product at a time should be prepackaged in a specific work area.

- Before beginning a prepackaging run, a physical evaluation (color, odor, appearance, and markings) of the medicine product being prepackaged should be made to assure product integrity. The bulk container should also be examined for evidence of damage, contamination, and other deleterious effects.
- All prepackaging equipment and systems should be operated and used in accordance with the manufacturer's or other established instructions.
- There should be valid justification and authorization by the supervisor for any deviation from those instructions on the part of the operator.
- The pharmacy professional must use available data on the characteristics of all packaging material used to protect the integrity of the medicine product.
- This information should include data on the chemical composition, light transmission, moisture permeability, size, thickness (alone or in laminate), recommended sealing temperature, and storage requirements.

☞ The main advantages of prepackaging medicines is that it allows enough time for patient counseling and minimizes dispensing errors resulting from hectic operation due to heavy patient load. Unfortunately, the materials commonly used for repackaging in many medicine retail outlets of Ethiopia are ordinary papers and the labeling is incomplete. In such cases, repackaging of medicines is likely to have many disadvantages than advantages.

Packaging aids and materials

☞ The materials used for repackaging include: glass bottles, plastic bottles, collapsible tubes, paper envelops, plastic envelops, etc.

☞ Paper has the least value as the primary packaging material in terms of maintaining the quality, safety and stability of packaged medicine.

Table: Packaging materials for medicine dispensing

Category of packaging*	Package characteristics	Examples
Tablets/capsules		
Desirable	Clean, dry, plastic or glass container with tight-fitting cap or seal	Blister packages, plastic sachets, tightly sealing plastic or glass containers with screw or snap cap
Acceptable	Clean, dry container that provides protection from dirt and moisture	Zipper-lock plastic bags, glycine paper, tin with tight-fitting lid
Undesirable	Unclean absorbent paper, cotton, cardboard containers with no provision for closure	Unsealed plastic bags, paper bags, newspaper or other printed paper
Liquids (oral and topical)		
Desirable	Clean, dry, light-resistant glass container with tight-fitting cap	Amber or opaque bottle with screw cap
Acceptable	Clean, dry plastic or glass container with tight-fitting cap	Glass or plastic bottle with tight-fitting cap
Undesirable	Unclean paper, cardboard, metal, or plastic (not formed) container with no provision for closure	Previously used liquid-containing cartons, plastic-lined paper bags, plastic bags
Liquids (otic and ophthalmic)		
Desirable	Clean (preferably sterile), light-resistant glass or plastic container with a dropper incorporated into a tight-fitting cap or a top fitted with a dropper with a protective sleeve	Amber dropper bottle, opaque plastic dropper bottle
Acceptable	Clean, dry plastic or glass container with tight-fitting cap and a clean plastic/glass dropper (separate)	Glass or plastic bottle with tight-fitting cap, glass or plastic dropper with protective container (cardboard, zipper-lock, plastic, or paper)
Undesirable	Anything other than above	Anything else
Creams/ointments		
Desirable	Clean glass or porcelain wide-mouth jar with tight-fitting lid or collapsible plastic or metal tube	Wide-mouth jar with tight-fitting lid, cream or ointment tube with cap
Acceptable	Clean glass or porcelain jar with lid	Glass or porcelain jar
Undesirable	Anything other than above	Anything else

* *Desirable:* Packaging should meet listed requirements for a period greater than 30 days.
Acceptable: Packaging should meet listed requirements for up to 30 days.
Undesirable: Packaging provides no protection from dirt, moisture, or other contaminants, thus permitting rapid deterioration or contamination.

5.9 **Provision of medicine information to patients**

Provision of information to patients

Many patients do not take the prescribed medicines correctly or regularly or do not take them at all for the following reasons:

- Complicated dosage schedule
- The medicines not perceived as effective
- Disappearance of symptoms
- Occurrence of side effects.
- Pill burden
- Inadequate information

Patient non-compliance may not have serious consequences for medicines with long plasma half-lives, but effectiveness will highly compromised with medicines having short plasma half-lives.

Patient compliance may be improved by:

- Prescribing a carefully selected essential-medicine:
  - Creating a good prescriber patient relationship, established through respect for the patients feeling and idea, thereby making the patient treatment partner

- Providing the necessary information:
  - The information should provide the knowledge to accept and follow treatment, and to acquire the necessary skills to take the medicine as prescribed.
  - The information should be given clearly in a language the patient understands, and should be checked whether the patient has understood the information correctly by letting him/her to repeat it in his/her own word.
- The minimum information that should be provided to patients include:
  - **Therapeutic effects**
    - the role of the medicine
    - disappearance of symptoms
    - onset of action
    - consequences of stopping the medicine or using it incorrectly
  - **Instructions**
    - dose of the medicine
    - route of medicine administration
    - time of medicine administration
    - frequency of medicine administration
    - duration of medicine administration
    - medicine storage conditions
  - **Side effects**
    - types of the side effects
    - ways of recognizing the side effects
    - duration of the side effects
    - seriousness of the side effects
    - actions to be taken
  - **Precautions**
    - drug-drug interaction
    - drug-disease interaction
    - Food-medicine interaction
    - maximum dose
    - the need for full treatment course

- **Contraindication**
  - History of hypersensitivity
  - Pregnancy
  - Age
- **Future consultations**
  - date of next appointment if needed
  - circumstances in which coming earlier is needed
- **Clarity of the information**
  - Re-checking whether the information is understood
  - allowing patients to ask some more questions

General Steps of Counseling

Counseling of patients on medications is an integral part of the medicines dispensing process. Lack or improper counseling by dispensers leads to incorrect use of medicines by patients which in turn results in loss of efficacy or occurrence of adverse effects. Professionals who are engaged in dispensing practice should be able to equip themselves with up-to-date medicine information.

Communication skill with patients or healthcare providers to convey relevant medicine information effectively and clearly necessary. All information provided to patients should be by the language the patient or the care provider can understand. Dispensers should check whether the information is understood by patients or their caregivers and correct any misunderstanding before they leave the dispensary.

- The information in the form of verbal or written instructions should include the following:

1. Check for any allergies in general and this medicine in particular
   - Ask for any allergies
   - Obtain past medicines use history
2. Tell name and indication of the medicine:
   - Name is important in case of emergency and visit to more than one provider
   - Indication reinforces diagnosis and creates confidence
3. Tell route and frequency of administration:
   - Prevents taking by the wrong route
   - Inform if first time or reinforce what they know
   - NB: ‘take one tablet after meal’ may not work since not everyone eats three meals a day.

4. Discuss on what to do if clients miss a dose or if the dose is vomited
5. Tell the client how long to take the medicine :
    - Helps to eliminate unrealistic expectations
    - Ensures reaching treatment goals
    - Prevents emergence of microbial resistance (for antibiotics)
6. Tailor medicine regimen to daily routine:
    - Ask the daily routine before suggesting a plan
    - Link taking a dose with regular daily task and effect of the medicine
    - Should not assume a common routine (e. g. eating three meals a day, sleeping night times, etc. which do not have fixed times)
7. Ask if the client has problem taking this medicine:
    - Complexity to the dosage regimen affects adherence:
    - Is there special preference for a dosage form when for example there is swallowing difficulty due to esophageal ulcers
    - Consider total cost of care not just the cost of the drug alone
8. Tell how long it will take for the medicine to show an effect:
    - If not told, the client may believe the medicine is not working and may stop taking or increase dose with subsequent toxicity
9. Tell how many times and when to refill:
    - Number of refills: Check if there is incontinence
10. Emphasize benefits of the medicine:
    - Discuss benefits before potential side – effects
11. Discuss major side effects of the medicine :
    - Side effects that are common and how long they will stay; those that disappear with time using reassurance can help to cope with them.
    - Measures to recognize, prevent, or manage side effects and adverse effects:
    - Tell what to do if side effects don’t go away or become intolerable
    - Encourage the patient to report side effects or adverse effects of the drugs
12. Discuss drug – drug, drug –food, drug- disease, drug – herb interactions

- Ask if client is taking other medicines, discuss interference of other drugs, food or medical conditions with current medicine and /or condition being treated.

13. Inform clients of devices that can assist them in taking their medications regularly and thereby improve adherence.
    - Alarm devices (wrist watch or cell phone alarms), pill boxes, associating doses with daily activities, leaving medications out where they can see them, etc.
14. Discuss precaution and measures to improve treatment outcome
    - Decreased salt intake, dietary requirement, self-monitoring, activities to be avoided
    - Don't assume client may have prior information, good to repeat and discuss precautions
15. Discuss storage recommendation supplementary instructions:
    - Shake well, refrigerate, avoid heat and humidity, etc.
    - Duration of use after opining container
16. Discuss religious and cultural issue that may affect medicines use
    - Fasting and holy water,
    - Dosage forms preferences,
    - The ill consequences of hoarding medicines at home and sharing of such medicines
17. Demonstrate and provide adequate information about special dosage forms:
    - Metered dose inhalers, suppositories, eye drops, ear drops, topical, transdermal patches, injections, sublingual tables, nasal sprays, sustained-release tablets/capsules, etc.
18. Educate techniques for self – monitoring; Examples:
    - Diabetes signs and symptoms of hypo- and hyper – glycaemia or use of blood glucose monitoring devices
    - Watch for excessive bleeding in warfarin therapy
    - Hypertension: use of blood pressure meters
19. Ask if there are any additional concerns or questions; listen respectfully and carefully.
20. Ask client to repeat key information to check how instructions are understood:
    - Could you tell me how you are going to take your medicine?
    - Praise good medication taking behavior to reinforce adherence
21. Provide your telephone number and encourage to contact you, if the need arises. Techniques for interacting with customers on the telephone include:

☼ using a pleasant and courteous manner

- ☼ stating the name of the pharmacy and your name
- ☼ following the standard procedure indicated for your pharmacy
- ☼ referring all calls that require a pharmacist's judgment to the pharmacist

Case study: Mr.X is a 40 years old teacher who has stage IV HIV/AIDS. He is has just been started on ART with the following regimen: AZT, 3TC and EFV.

Illustration: HIV is a chronic viral infection that leads to severe immune deficiency, which will ultimately leads to death if left untreated. There is no cure for HIV yet but there are nowadays very effective medicines, which suppresses multiplication of the virus. This results in boosting the immunity of the patient and ultimately prevents the occurrence of life threatening opportunistic Infections and hence prolongs survival. The treatment is however complex and it has to be taken life- long. Therefore there is a significant risk that many patients may not take their medicine as prescribed. Hence adequate and appropriate information should be given to such patients as follows:

- The medicine suppresses multiplication of virus & results in boosting immunity.
- Takes one tablet of each AZT 300mg, 3TC 150mg twice a day and EFV 600mg at night for two weeks To take their medicines daily exactly as prescribed and not stop taking the medicines unless otherwise instructed to do so
- Advise your patients to follow a regular time for their medicine administration
- Warn patients for common side effects of the medicines. For instance, AZT may lead to profound anemia and some GI upset. EFV is often associated with some CNS side effects ranging from simple sleep disturbance to frank psychosis. Reassure them that most of these side effects will disappear after a couple of weeks. However in those patients with severe symptoms, they should be advised to report early.
- Patient also should be advised not to drink alcohol, chew chat, smoke cigarette and have unprotected sex
- Underline the importance of having a regular follow up. This will help the treating physician not only to evaluate patient's response to treatment but will also enable him/her to monitor for medicine side effects.
- Avoid fatty meal for EFV

Dosage Form Specific Dispensing Procedures

Tips for Proper Dispensing of Pediatric Powder for Suspension for Oral Use

- Use freshly boiled and cooled water (FBC)
- Add the FBC gently bit by bit shaking each time after each bit and finally exactly to the mark on the bottle.
- FBC is added only once to each bottle
- Do not add water (FBC) to all bottles at the same time, meaning this has to be only after the first reconstituted bottle is completed
- Shake each time before use
- Use only volume measuring device recommended by the dispenser to pour the accurate dose
- 'Do not use after _____days
- Provide the general warnings and find recommended warning label wordings that apply to a specific drug
- Praise your child for becoming willing to take the dose and the fact syrups are not candies but harmful medications if taken inappropriately

Counseling Points for Administration of Eye Drops

- Wash your hands. Emphatically advice the need for thorough hand washing before application and importance of eye hygiene in prevention of contamination of the remaining doses and avoidance of re-infection and relapse of the problem.
- Open the closure. Do not touch the dropper opening.
- Look upward.
- Pull the lower eyelid down to make a ‘gutter’.
- Bring the dropper as close to the `gutter' as possible without touching it or the eye.
- Apply the prescribed amount of drops in the ‘gutter’.
    - Be vigilant on the issue of systemic side effects after application into the eye.
    - Educating the patient on the needs to close the tubes immediately after each use
- Close the eye for about two minutes. Do not shut the eye too tight; Excess fluid can be removed with a tissue.
- Eye-drops may cause a burning feeling but this should not last for more than a few minutes. If it does last longer consult a doctor or dispenser.

- If more than one kind of eye-drop is used wait at least five minutes before applying the next drops.
- When giving eye-drops to children:
    - Let the child lie back with head straight.
    - The child's eyes should be closed.
    - Drip the amount of drops prescribed into the corner of the eye.
    - Keep the head straight.

  Important!!!!
    - Identify the type of eye preparation (lotion, solution, ointment, etc.)
    - Eye drops are generally instilled into the pocket formed by gently pulling down the lower eyelid and keeping the eye closed for as long as possible after application;
    - One drop is all that is needed. A small amount of eye ointment is applied similarly; the ointment melts rapidly and blinking helps to spread it.
    - When two different eye-drop preparations are used at the same time of day, dilution and overflow may occur when one immediately follows the other. The patient should therefore leave an interval of at least 5 minutes between the two.

Counseling Points for Administration of Eye ointment

- Wash your hands.
- Tilt the head backwards a little.
- Take the tube in one hand, and pull down the lower eyelid with the other hand, to make a ‘gutter’. Do not touch anything with the tip of the tube.
- Bring the tip of the tube as close to the ‘gutter’ as possible.
- Apply the amount of ointment prescribed.
- Close the eye for two minutes.
- Remove excess ointment with a tissue.
- Clean the tip of the tube and close it.

Counseling Points for Administration of Ear drops

- Warm the ear-drops by keeping them in the hand or the armpit for several minutes. Do not use hot water tap, no temperature control!
- Tilt head sideways or lie on one side with the ear upward.
- Gently pull the lobe to expose the ear canal.

- Apply the amount of drops prescribed.
- Wait five minutes before turning to the other ear.
- Use cotton wool to close the ear canal after applying the drops ONLY if the manufacturer explicitly recommends this.
- Ear-drops should not burn or sting longer than a few minutes. If it does last longer consult a doctor or dispenser.

Counseling Points for Administration of Nasal drops

- Blow the nose.
- Sit down and tilt head backward strongly or lie down with a pillow under the shoulders; keep head straight.
- Insert the dropper one centimeter into the nostril.
- Apply the amount of drops prescribed.
- Immediately afterward tilt head forward strongly (head between knees).
- Sit up after a few seconds; the drops will then drip into the pharynx.
- Repeat the procedure for the other nostril, if necessary.
- Rinse the dropper with boiled water.

Counseling Points for Administration of Nasal spray

- Blow the nose.
- Sit with the head slightly tilted forward.
- Shake the spray.
- Insert the tip in one nostril.
- Close the other nostril and mouth.
- Spray by squeezing the vial (flask, container) and sniff slowly.
- Remove the tip from the nose & bend the head forward strongly (head between knees).
- Sit up after a few seconds; the spray will drip down the pharynx.
- Breathe through the mouth.
- Repeat the procedure for the other nostril, if necessary.
- Rinse the tip with boiled water.

Counseling Points for Administration of Aerosol

- Cough up as much sputum as possible.
- Shake the aerosol before use.

- Hold the aerosol as indicated in the manufacturer's instructions (usually upside down).
- Place the lips tightly around the mouthpiece.
- Tilt the head backward slightly.
- Breathe out slowly, emptying the lungs of as much air as possible.
- Breathe in deeply and activate the aerosol, keeping the tongue down.
- Hold the breath for ten to fifteen seconds.
- Breathe out through the nose.
- Rinse the mouth with warm water.

Counseling Points for Administration of Suppositories

- Defecate and wash your hands.
- Remove the covering (unless too soft).
- If the suppository is too soft let it harden first by cooling it (fridge or hold under cold running water, still packed!) then remove covering.
- Remove possible sharp rims by warming in the hand.
- Moisten the suppository with cold water.
- Lie on your side and pull up your knees.
- Gently insert the suppository, rounded end first, into the back passage.
- Remain lying down for several minutes.
- Wash your hands.
- Try not to have a bowel movement during the first hour.

Counseling Points for Administration of Vaginal tablet with Applicator

- Wash your hands.
- Remove the wrapper from the tablet.
- Place the tablet into the open end of the applicator.
- Lie on your back, draw your knees up a little and spread them apart.
- Gently insert the applicator with the tablet in front into the vagina, do NOT use force!
- Depress the plunger so that the tablet is released.
- Withdraw the applicator.
- Discard the applicator (if disposable).
- Clean both parts of the applicator with soap & boiled, lukewarm water (if reusable).
- Wash your hands.

Counseling Points for Administration of Vaginal tablets without applicator

- Wash your hands.
- Remove the wrapper from the tablet.
- Dip the tablet in lukewarm water just to moisten it.
- Lie on your back, draw your knees up and spread them apart.
- Gently insert the tablet into the vagina as high as possible, do NOT use force!
- Wash your hands.

Counseling Points for Applying vaginal creams ointments and gels (Most of these drugs come with applicator)

- Wash your hands.
- Remove the cap from the tube containing the drug.
- Screw the applicator to the tube.
- Squeeze the tube until the required amount is in the applicator.
- Remove the applicator from the tube (hold the cylinder).
- Apply a small amount of cream to the outside of the applicator.
- Lie on your back, draw your knees up and spread them apart.
- Gently insert the applicator into the vagina as far as possible, do NOT use force.
- Hold the cylinder & with other hand push plunger down thus inserting drug into vagina.
- Withdraw the applicator from the vagina.
- Discard the applicator if disposable or clean thoroughly (boiled water) if not.
- Wash your hands

5.10 **Finalize prescription and documentation**

- Prescriptions should be recorded and documented as proof of transaction between the patient and the dispenser.
- Prescriptions can therefore be traced back if any need arises. All dispensing units should have a standardized Prescription Registration Book (PRB) for recording every pharmaceutical issued to a patient (table below).
- A computerized dispensing and registration system may also be used, but should always be supported by paper back up.
- The PRB should be completed at the time of dispensing or at close of working day.

- The prescription registration book should be used both when prescriptions are retained in the pharmacy and when they are returned to the patient.
- For a prescription which is returned to a patient because all the items in the original prescription could not be filled, the medicines that have been dispensed from the pharmacy should be copied on a blank prescription and the prescription should be filed appropriately.
- On the original prescription, which is retained by the patient, the word "dispensed" should be stamped adjacent to those items which have been dispensed.
- For prescriptions which are to be refilled on a later date, dispensing information should be entered into the registration book before returning the prescription to the patient.
- The official seal of pharmacy/Health institution, name and signature of dispenser, date of dispensing and the next refill date should be written on the back of the prescription.

Documentation and report

- The receipts for requisition, receiving as well as the prescription registration book should be kept properly.
- Blank prescription should be kept carefully, only prescribers have access to them.
- Filled prescription should be kept as a receipt.
- Prescriptions for narcotic and psychotropic Substances should be kept for 5 years and other prescriptions for 2 years. Thereafter, they should be disposed carefully in the presence of appropriate body.
- Regular reports on medicine consumption and prescribing pattern from patient prescription registration book should be prepared and report to appropriate body timely.
- Information obtained from prescription registration book could be used for further planning and efficient utilization of resource.
- The report on physical inventory shall be documented.

☞ **Dear Learner tries to refer Prescription Registration Format from the Annex**

Self – Check

Short answer

1. Mention the six procedures of processing prescription?
2. Mention the Prescription Contents?
3. What are the criteria you use to evaluate a prescription?
4. Mention the information that should be included on label?

Multiple Choices

1. The patient was under IV infusion of malarial treatment with the drops of medicine that pours at the rate of 10drops/ml of 1L volume and finished within 4hrs.What was the rate of the IV infusion

   A. 4.2 drops/min C.84 drops/min

   B. 42 drops/min D.22 drops/min

2. Prednisolone each tablet containing 5mg. Start 40 mg and then taper by 5mg every day for 8 days. How many tablets are dispensed for this client?

   A. 8 tablets B. 16 tablets C.36 tablets D. None of the above

3. PPF 400,000IU IM/day for 7days.How many vials should be dispensed for this patient?

   A. 2 B.0.5 C.1 D.3

4. One of the following is NOT the responsibility of dispenser?
   A. Checking the legality of the prescription
   B. Labeling of medicines
   C. Counseling of the patient
   D. Prescribing of medicines

5. For PCP adjunctive treatment Prednisolone 40mg BID for 5 day, then 40mg QOD for 5 days, then 20mg QD for 11 days. If the available dose of prednisolone is 10mg. Calculate total prednisolone dispensed for 21 days?

   A. 74 B.62 C.82 D.92

7. One of the following prescription information is used to adjusting of the dose of the drugs?

   A. Sex B. Age C. Address D. Diagnosis

Summary

Assisting in prescription preparation practices ensure that an effective form of the correct medicine is delivered to the right patient, in the correct dosage and quantity, with clear instructions, and in a package that maintains the potency of the medicine. Dispensing includes all the activities that occur between the time the prescription is presented and the time the medicine or other prescribed items are issued to the patient.

A safe, clean, and organized working environment provides a basis for good practice. Dispensing must be performed accurately and should be done in an orderly manner, with disciplined use of effective procedures.

Care should be taken to read labels accurately. The dispenser must count and measure carefully and guard against contamination of medicines by using clean equipment and never allowing skin contact with the medicines.

Staff members who dispense must be trained in the knowledge, skills, and practices necessary to dispense the range of medicines prescribed at the facility. Their performance should be regularly monitored.

Prepackaging medicines can improve efficiency in dispensing. Dispensing can also be improved by routine procedures for safety checking before issuing medicines to patients.

Cost factors inevitably lead to the use of packaging that is less than ideal. The packaging used must be the best compromise between cost and the risk of waste, with regard to maintaining standards of cleanliness.

Labeling is also affected by cost. Labels should contain information about the medicine and its correct use. The style and language of labeling should be appropriate to the needs of the patient.

Ensuring patients' understanding of how to take their medicines is a primary responsibility of dispensers. Dispensers should check understanding by asking each patient to repeat instructions.

Good records, though sometimes neglected, are an essential part of dispensing; they facilitate good management and monitoring of services provided.

Learning activity Performance test

Critical aspects of the competencies

Knowledge

- ✓ Hospital or health facility in-house computer system
- ✓ Identification and handling of products, including
  - formulary drugs and non-formulary drugs e.g. clinical trial drugs and special access scheme drugs
  - products with the required integrity as well as those whose integrity has been compromised e.g. damaged, contaminated or deteriorated stock
- ✓ Knowledge of and the rationale for applicable legislation, organization policy and in house standard operating procedures (SOPs), relating to prescription preparation.
- ✓ Legal requirements and principles of pharmaceutical product labeling e.g. product name, batch numbering and expiry date
- ✓ Procedures and rationale for validating prescriptions
- ✓ Procedures to follow regarding dispensing of controlled drugs
- ✓ Properties of container types and principles of selection for use
- ✓ Requirements to be satisfied for a complete, unambiguous and valid prescription and actions to take if validity is questionable
- ✓ Types of prescriptions and their use

Skill

- ✓ Assist pharmacist effectively in the preparation of prescription requirements
- ✓ Follow instructions and complete tasks accurately and efficiently
- ✓ Refer issues identified outside scope of practice to the appropriate person
- ✓ Work in accordance with relevant organization policy, legislative requirements, industrial awards and agreements and in-house operating procedures (SOPs)
- ✓ Apply checking processes throughout dispensing procedure
- ✓ Create labels which are legal, clearly readable, with instructions expressed in simple language, including all information specified by the prescriber
- ✓ Demonstrate safe dispensing practices
- ✓ Enter and access data on pharmacy computer system
- ✓ Identify discrepancies/deviations and refer to the authorized person
- ✓ Identify drugs by generic and proprietary names, or readily access the information

- ✓ Identify & select correct product with reference to form, dose, strength, and quantity.
- ✓ Use ancillary and cautionary labels and explanatory statements and directions as specified by most recent Ethiopian National Drug Formulary (ENDF)
- ✓ Use time management strategies to set priorities
- ✓ Use literacy, numeracy and oral communication skills required to fulfill the position in a safe manner as specified by the health care facility
- ✓ Use problem solving skills
- ✓ Use available resources and prioritize workload

5.11 **Additional reading materials**

1. Manual for Medicines Good Dispensing Practice,FMHACA,2nd Edition ,2012
2. Manual for Good Prescribing Practice,FMHACA,2nd Edition,2012
3. Managing Access to Medicines and Health Technologies, Management Sciences for Health, 2012.
4. APTS Training Course Participant's Guide
5. American Pharmacist Association Basic Pharmacy and Pharmacology Series for Pharmacy Technician 4th Edition, 2010.

Module Syllabus

Module title: Dispensing of Pharmaceuticals-II

Module code: PHA 3 M1 1017

Nominal duration: 240 hrs (5 weeks) Theory 160 hrs. Practice 80 hrs.

Module Description: This module aims to provide the learners with the knowledge, skills and right attitudes required to undertake pharmacy hospital/community assisting work in the hospital/community pharmacy environment, including working effectively within the organization structure, policies and procedures, legislative requirements, hospital pharmacy services and hospital pharmacy assistant practices. In addition this module is concerned with the assistance with preparation of prescriptions, package and/or prepackage pharmaceutical products in accordance with Ethiopian good dispensing practice in Hospitals and national guidelines/legislation on the filling of dose administration containers and Good Pharmacy Practice requirements.

Unit of Competencies:

HLT PHA 3 01 0611 Orientation to Hospital Pharmacy Services and Hospital Pharmacy Assistant Practices

HLT PHA 3 03 0611 Assist with Prescription Preparations

Module Outcomes

At the end of the module the learner will be able to:

- Work effectively within the Hospital and community pharmacy environment
- Maintain pharmaceutical quality assurance requirements
- Follow relevant pharmaceutical legislation and regulations
- Perform the duties of hospital/community pharmacy assistant
- Accept prescription for dispensing
- Calculate prescription quantities and provide information for the client
- Prepare labels according to legal requirements
- Assemble prescription items according to good dispensing practice
- Finalize prescription and documentation

Teaching/learning methods

- Interactive lecture
- Demonstration
- Case study
- Group discussion
- Observation of health facility and activity

Teaching/learning materials

- Learning module
- Reference book
- Checklists
- Guidelines
- Standard operating procedures
- Policy and legislation
- Dispensing manual
- Audiovisuals
- Mini pharmacy
- Packaging and labeling materials
- Prescription paper
- Ethiopian Pharmaceutical Code of ethics
- Drug counseling guide line
- Good dispensing practice manual

Methods of assessment

- Oral examination
- Written examination
- Structured observation
- Group assignment
- Report

Dispensing Medication II Module schedule

Week	Learning Activity	Required Reading / Assignment
Week 1	**Day 1** **<u>Interactive lecture (2 hours)</u>** • Introduction • Health Delivery system in Ethiopia • Definition of hospital • History of Hospital • Classification and function of hospital • Administration of hospital • Role and responsibilities of hospital staff **<u>Interactive lecture (2 hours)</u>** • Definition of hospital pharmacy • History of hospital pharmacy • Operational standards of hospital pharmacy services **<u>Interactive lecture (2 hour)</u>** • Organization of hospital pharmacy services • Pharmacy services organization and mgt **<u>Interactive lecture(2hour)</u>** • Drug information Services • Clinical pharmacy Services **Day 2** **<u>Interactive lecture (2 hours)</u>** • Resources needed for pharmacy services **<u>Interactive lecture(2 hours)</u>** • DTC **<u>Interactive lecture (4 hours)</u>** • DTC	Reading Assignment Reading assignment

	Day 3 **<u>Interactive lecture(2 hours)</u>** • **Community pharmacy** **<u>Interactive lecture(2 hours)</u>** • Organization • Scope • Role and responsibility of community pharmacy professional **<u>Interactive lecture (4 hours)</u>** • **Role & responsibilities of pharmacy assistant** **Day 4** **<u>Interactive lecture (4 hours)</u>** • Introduction to pharmaceutical quality assurance • Definition of key terms • Characteristics of comprehensive quality assurance program • Pharmaceutical quality assurance frame work **<u>Interactive lecture (4 hours)</u>** • Determinants of medicine quality • How Is Quality of Medicines Assessed and Assured • Who ensured medicine quality **Day 5** **<u>Interactive lecture (4 hrs)</u>** Techniques for quality medicine dispensing **Examination(3hrs)**	
Week 2	**Day 1** **<u>Interactive lecture and discussion(4 hours)</u>** • Introduction to pharmacy Ethics	

	• Definition of key terms **Interactive lecture and discussion(4 hours)** • Pharmaceutical law • Types of pharmaceutical law • Authority governing the practice of pharmacy in ethiopia **Day 2** **Interactive lecture (4 hours)** • Pharmaceutical code of ethics • Ethical Principles and Obligations of the Pharmacy professional with respect to other stakeholders during his/her professional Practice **Interactive lecture and discussion(4 hours)** • Ethical Principles and Standards in Pharmacy Practices • Ethical Principles and Obligations on Special Ethical Issues **Day 3** **Interactive lecture and discussion(2 hours)** • Drug Registration and Control **Interactive lecture and discussion(2 hours)** • Dissemination of Information and Advertisement • Packaging Materials and Label **Interactive lecture and discussion(4 hours)** • Narcotic Drugs and Psychotropic Substances • Poisons and Radiopharmaceuticals • The Twelve Principles of Ethics for General Public Service **Day 4** **Interactive lecture and discussion(2 hours)** o National Drug Policy

	Interactive lecture and discussion(2 hours) o Reading **Examination(3 hours)** **Day 5** **Interactive lecture and discussion(4 hours)** • Assisting prescription preparation • Accepting prescription for dispensing **Interactive lecture(4 hours)** • Definition of Prescription evaluation and interpretation • Criteria of prescription evaluation **Practice on prescription evaluation (3 hours)**

Day 1

Practice on prescription evaluation(7hours)

Day 2

Interactive lecture and exercise(7)

- Dosage calculation

Day 3

Exercise on dosage calculation(4hours)

Interactive lecture (3 hours)

- General Counseling steps

Day 4

Practice on Counselling(7 hours)

Day 5

Practice on Counselling(7 hours)

Day 6

Practice on Counselling(7 hours)

Day 1

Interactive lecture(4 hours)

- Labeling and Packaging

Practice(3 hours)

- Labeling and packaging

Day 2

Practice (7 hours)

- Labeling and packaging

Day 3

Interactive lecture(4 hours)

- Recording and filling prescription

Practice(3 hours)

Day 4

Practice(7 hours)

Day 5

Practice(7hrs)

- Six dispensing procedures(cycles)

Day 6

Practice(7 hours)

- Six dispensing procedures(cycles)

Day 1

Practice(7 hours)

- **Six dispensing procedures(cycles)**

Day 2

Practice(7 hours)

- **Six dispensing procedures(cycles)**

Day 3

Preparation for exam

Day 4 Exam

Reference Books

1. Manual for medicines good dispensing practice for Ethiopia,FMHACA,2012,2nd edition
2. William E.Wassan, Hospital Pharmacy, 3rd edition, 1997
3. K. Sampath; Hospital and Clinical Pharmacy, 3rd edition, 1998

4. Dianna M. Collette; Pharmaceutical Practice, 1989
5. Jon Watefield; Community Pharmacy Handbook; Leicester, UK
6. Auditable Pharmaceutical Transactions and Services (APTS) Training Manual for Ethiopia
7. Standard operating procedures (SOPs) manual for drug and therapeutics committee in health facilities of Ethiopia,2016
8. Ethiopian hospital services transformation guidelines, pharmacy services chapter September,2016